

Partnering to Prevent Hypoglycemia

November 1, 2017



Office of Disease Prevention
and Health Promotion

Hypoglycemia: Our Greatest Fear in Diabetes

**Why Patients and Their Loved Ones
Appreciate That You Have Convened
This Critically Important Meeting**

*Lorraine Stiehl
Diabetes Patient Advocate for 30 Years*

Patient Advocacy Roles

- Active Volunteer and/or Consultant for Numerous Diabetes Non-Profit Organizations Including **The diaTribe Foundation, Diabetes Research Connection, Diabetes Hands Foundation/Tu & Es Tu Diabetes, Diabetes Empowerment Foundation, Students & Young Adults With Diabetes**
- **JDRF**: National Volunteer Chair Grassroots Advocacy & Advocacy Committee Chair, International Board of Directors
- **NIH TrialNet & Diabetes Clinical Trials**: Recruitment Specialist, UCSF
- **CDC/FL Department of Health/USF**: Florida Diabetes Prevention Program Consultant
- **California Institute for Regenerative Medicine**: Advocate Consultant



What To
Do When
Your
Partner
Has
Diabetes:
A Survival Guide

by

Nicole Johnson, DrPH, MPH, MA

Miss America 1999

Living With Type 1 Diabetes Since 1993

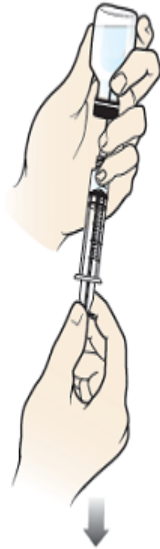
&

Lorraine Stiehl

Diabetes Advocate

Partner of a Loved One With Diabetes Since 1985







Soluble, Easy to Administer Glucagon



Hypoglycemia is a **SERIOUS** problem

JAMA Internal Medicine – March 10, 2014

97,648 emergency department (ED) visits for insulin-related hypoglycemia and errors (IHEs) occur annually in the US

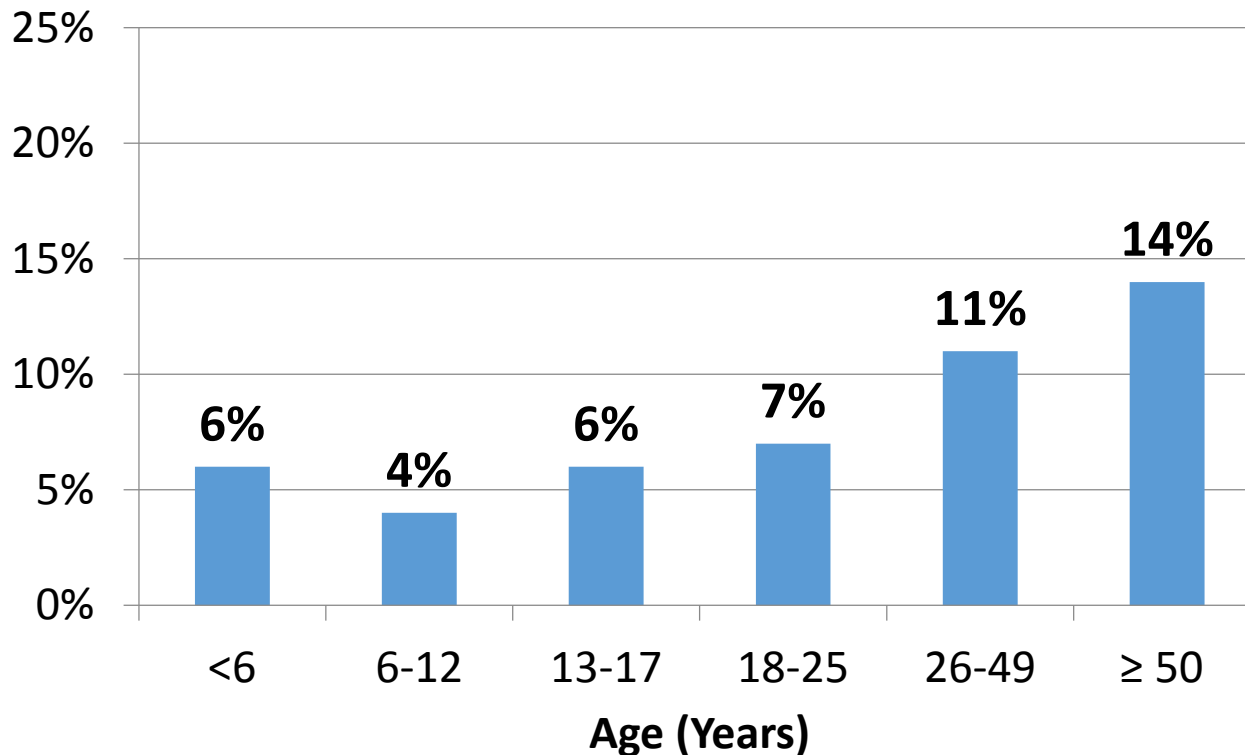
29% resulted in hospitalization

An estimated cost of **\$640 million**

At \$1,387 per ED visit and \$17,654 per hospitalization, per Quilliam et al., *AJMC* 2011.

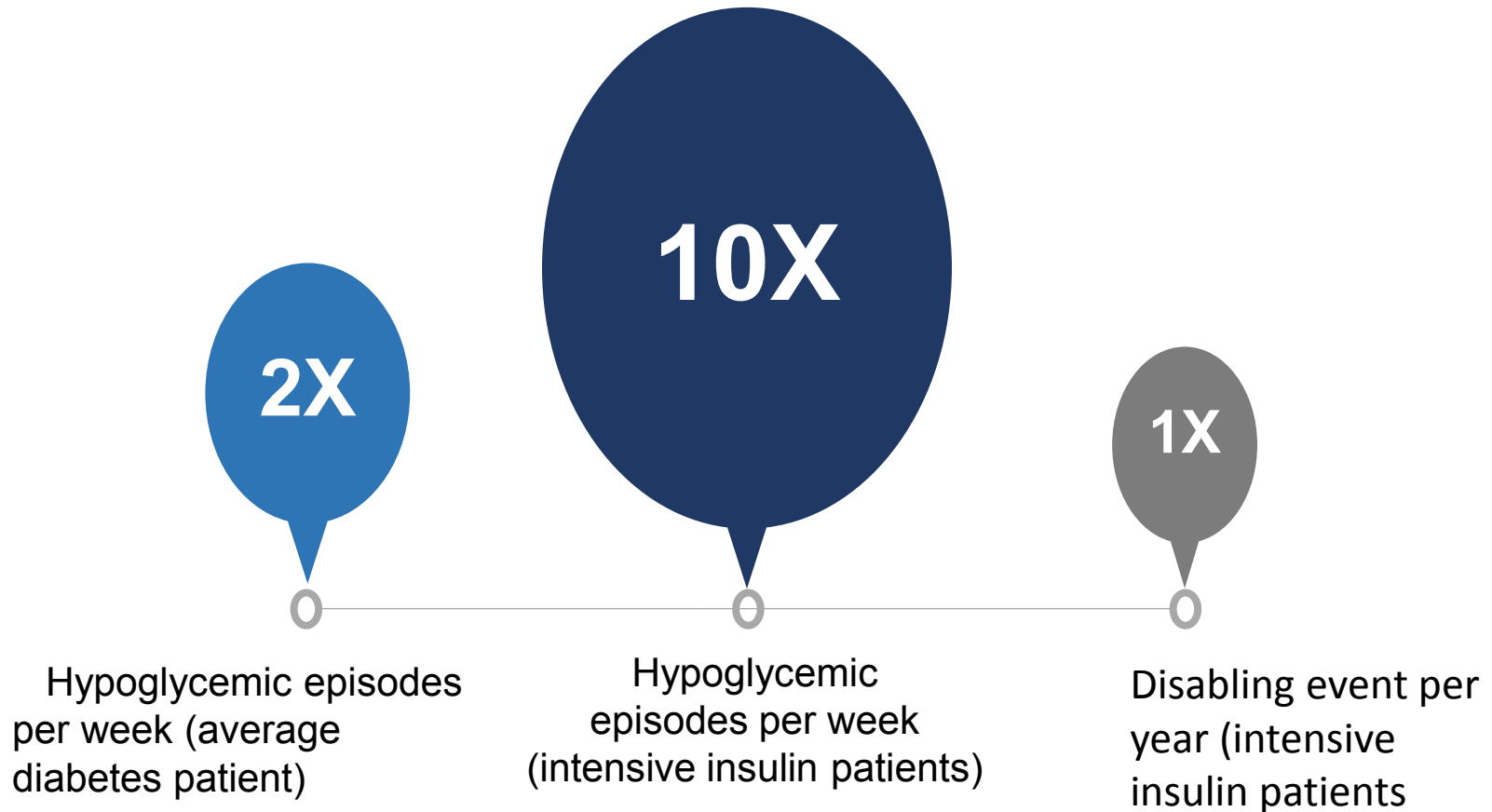
Severe hypoglycemia is far too common in type 1 diabetes

12-month Frequency of Severe Hypoglycemia
(seizure or coma/loss of consciousness)



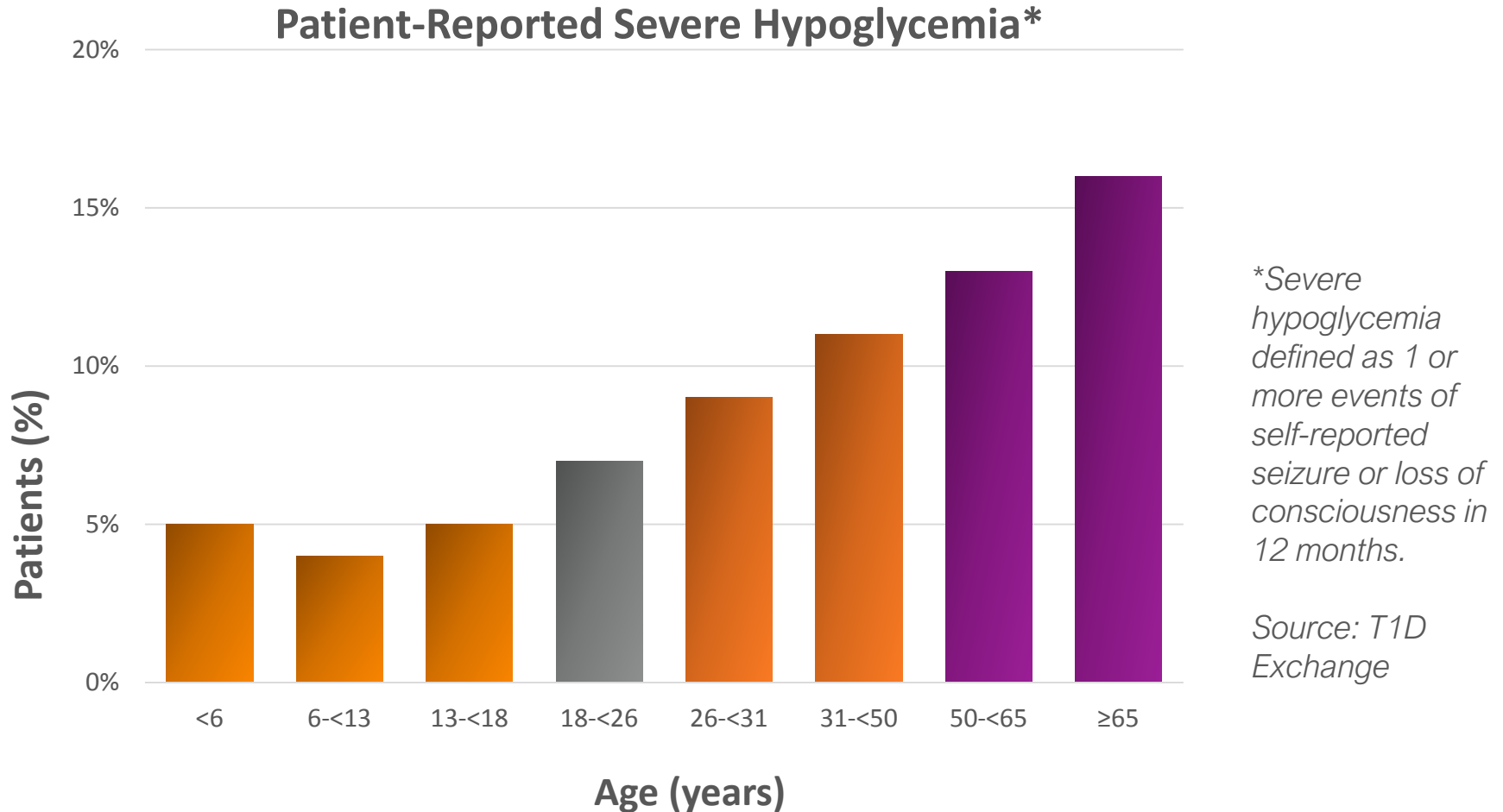
Source: The Helmsley Charitable Trust's
T1D Exchange

Severe Hypoglycemia is a problem in both type 1 and type 2 diabetes



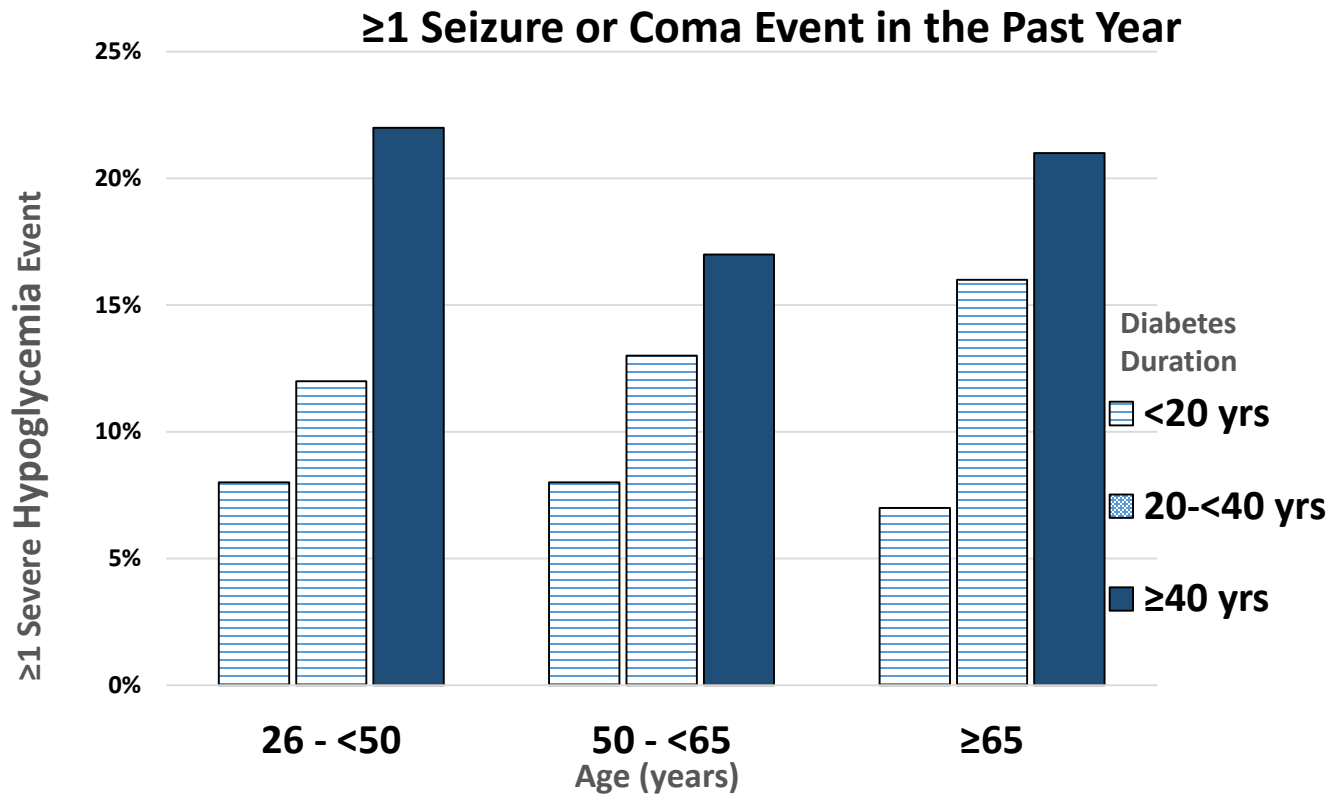
And these patients often never feel their low blood sugars

12-month frequency of severe lows by age



Roy W. Beck, William V. Tamborlane, Richard M. Bergenstal, Kellee M. Miller, Stephanie N. DuBose, Callyn A. Hall, for the T1D Exchange Clinic Network; The T1D Exchange Clinic Registry, *The Journal of Clinical Endocrinology & Metabolism*, Volume 97, Issue 12, 1 December 2012, Pages 4383–4389, <https://doi-org.unr.idm.oclc.org/10.1210/jc.2012-1561>

Longstanding T1Ds are at very high risk



Source: T1D Exchange

Ruth S. Weinstock, Dongyuan Xing, David M. Maahs, Aaron Michels, Michael R. Rickels, Anne L. Peters, Richard M. Bergenstal, Breanne Harris, Stephanie N. DuBose, Kellee M. Miller, Roy W. Beck, for the T1D Exchange Clinic Network; Severe Hypoglycemia and Diabetic Ketoacidosis in Adults With Type 1 Diabetes: Results From the T1D Exchange Clinic Registry, *The Journal of Clinical Endocrinology & Metabolism*, Volume 98, Issue 8, 1 August 2013, Pages 3411–3419, <https://doi-org.unr.idm.oclc.org/10.1210/jc.2013-1589>

Detecting Hypoglycemia

32%

of hypo
events
were
detected by
meter^{3*}

**Pediatric population
only*

55%

of severe
hypo events
occurred
during sleep
(DCCT)

Age
8-14

33%

49%

Age
15-24

of subjects had
≥ 1 episodes of nocturnal
hypoglycemia in a week¹
JDRF 2010 masked CGM study

Undetected nocturnal hypoglycemia...

...occurred in

>30%

of nights when
monitored with a
blinded CGM
device²

Despite
checking BG

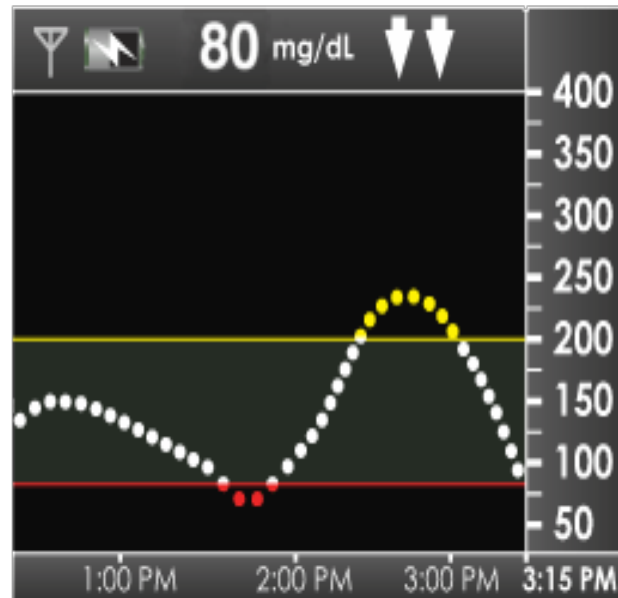
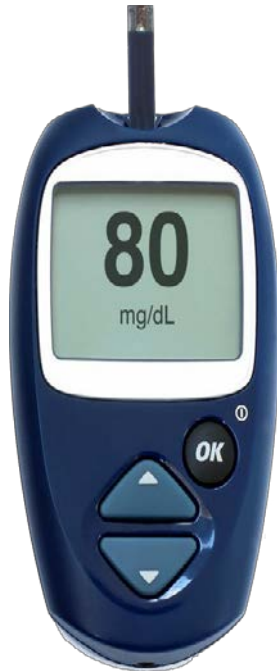
10x/day

98%

of nocturnal events were
asymptomatic

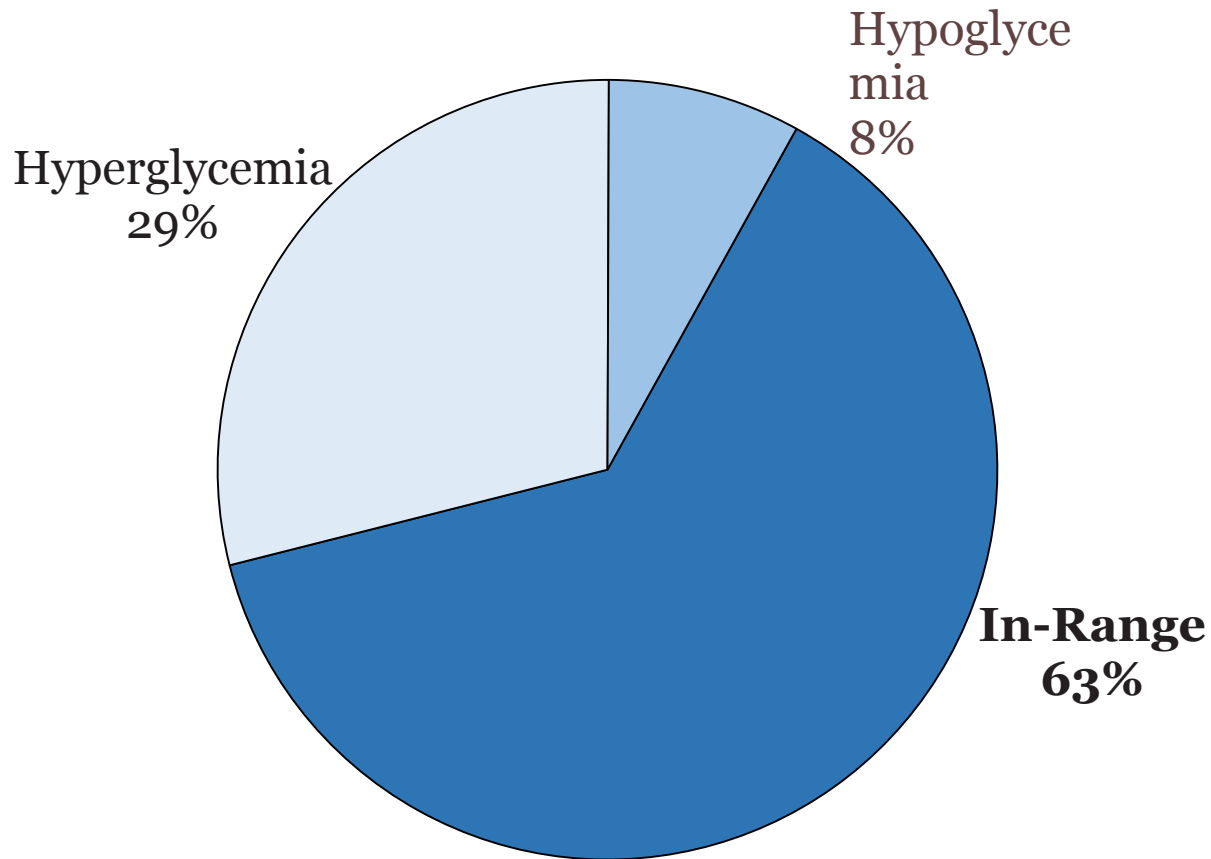
1. JDRF CGM Study Group: Prolonged nocturnal hypoglycemia is common during 12 months of continuous glucose monitoring in children and adults with type 1 diabetes. *Diabetes Care* 2010;33:1004–1008. 2. Bachmann, Sara, et al. "Nocturnal hypoglycemia and physical activity in children with diabetes: new insights by continuous glucose monitoring and accelerometry." *Diabetes care* 39.7 (2016): e95-e96. 3. Sundberg & Forsander, 2014, *Pediatric Diabetes*, 15; 34-40.

Patients & Partners Love Our Arrows!

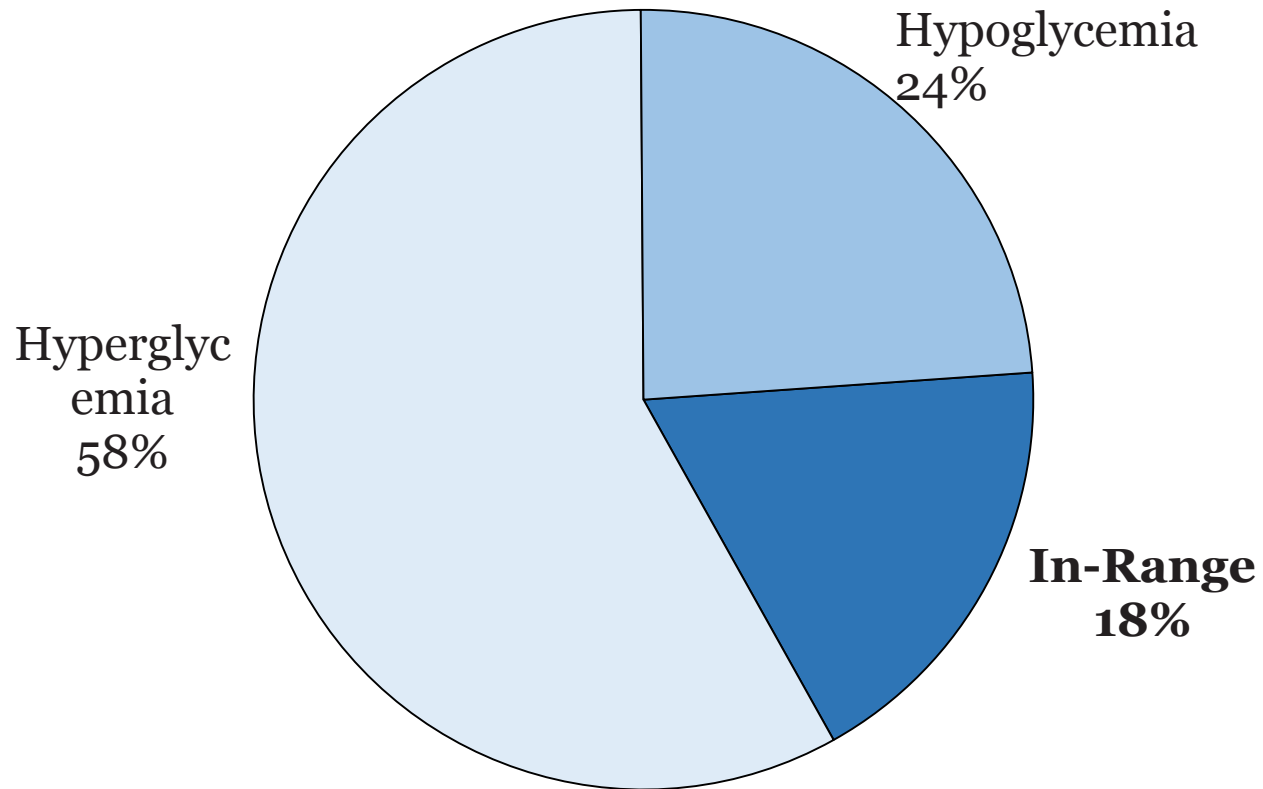


What a difference a picture makes!

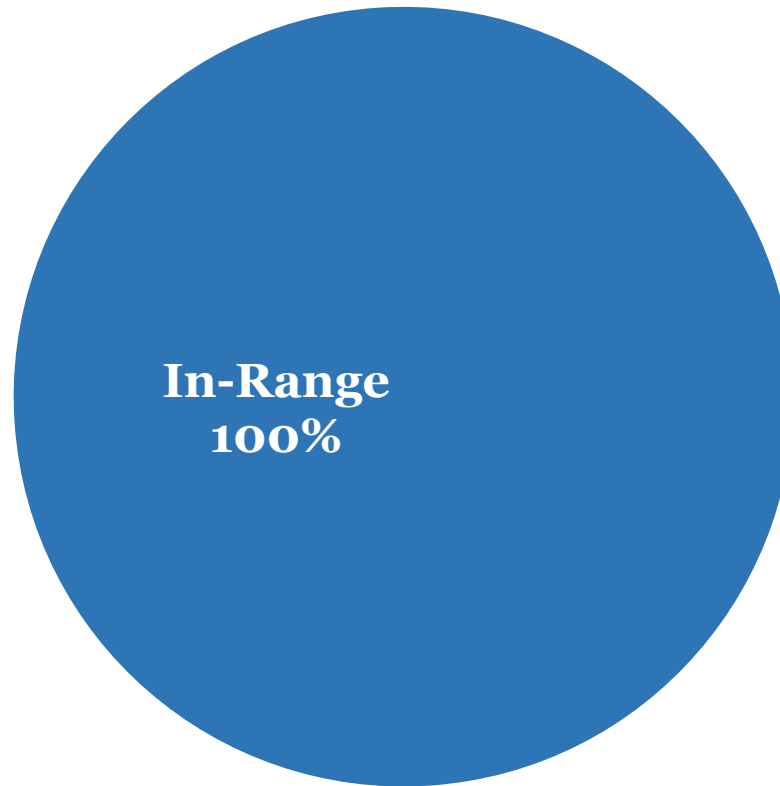
Example 1 – A1c of 7%



Example 2 – A1c of 7%



Example 3 – A1c of 7%



A1c does not tell the full story!

An A1c of 7% = average blood glucose of 154 mg/dl

| Range | Example 1 | Example 2 | Example 3 |
|-----------------|-------------|-------------|-------------|
| < 70 mg/dl | 8% | 24% | - |
| 70-180 mg/dl | 63% | 18% | 100% |
| > 180 mg/dl | 29% | 58% | - |
| Approximate A1c | 7.0% | 7.0% | 7.0% |

But time in range – and thus ‘quality of A1c’ – can be dramatically different!

Beyond A1C Meeting Objectives



- **Outline limitations of A1C and necessity to monitor other glycemic outcomes beyond A1C**
- **Communicate consensus from [ADA 2017 Scientific Sessions](#) on key non-A1C glucose metrics (i.e., hypoglycemia, hyperglycemia, time in zone, etc.) to support regulatory and research focus**
- **Communicate utility of these glycemic endpoints and understand what evidence is needed for validation**
- **Discuss the implementation of non-A1C glucose metrics and education of health care providers and patients**
- **Propose that non-A1C metrics derived from CGM technology are suitable for providing regulatory-grade evidence**

**Source: The diaTribe
Foundation**

Most people with type 1 diabetes spend little time “in range”

A seven-center, 21-day CGM study found that:

People with type 1 diabetes were found to be
“in the optimal ADA glycemic range” only

28% of the time,

on average spending over

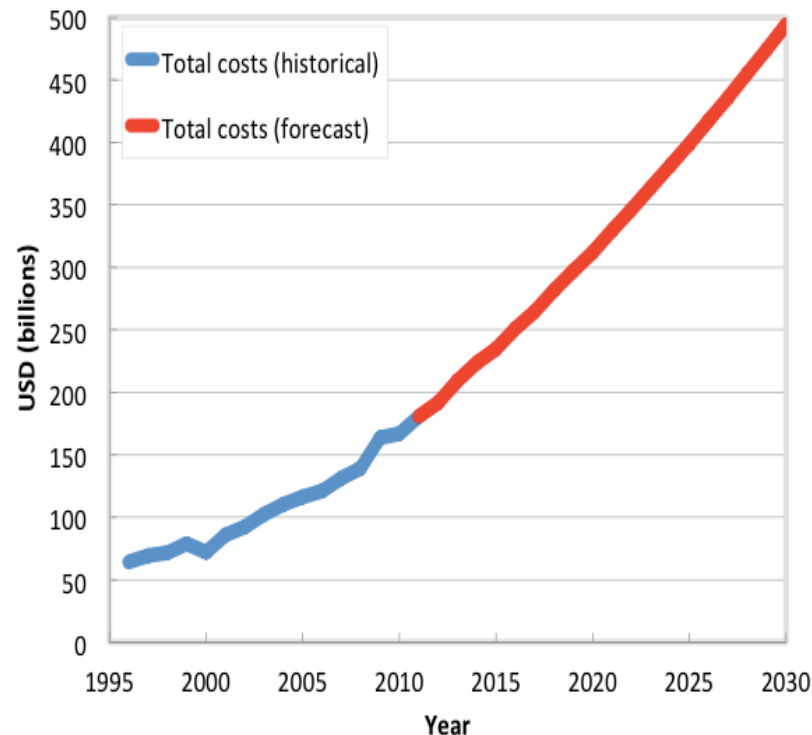
2 hours/day in hypoglycemia



Special Request of CMS

Diabetes is an Urgent Need

Annual diabetes-related healthcare spending is forecast to reach nearly \$500 billion by 2030



Source: Chen et al., 142-LB, ADA 2014

LORRAINE STIEHL

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Hearing the Patient

What are the wants and needs of the Patient?

Chris Stiehl

67 years old; 57 years of type 1 diabetes (T1D)



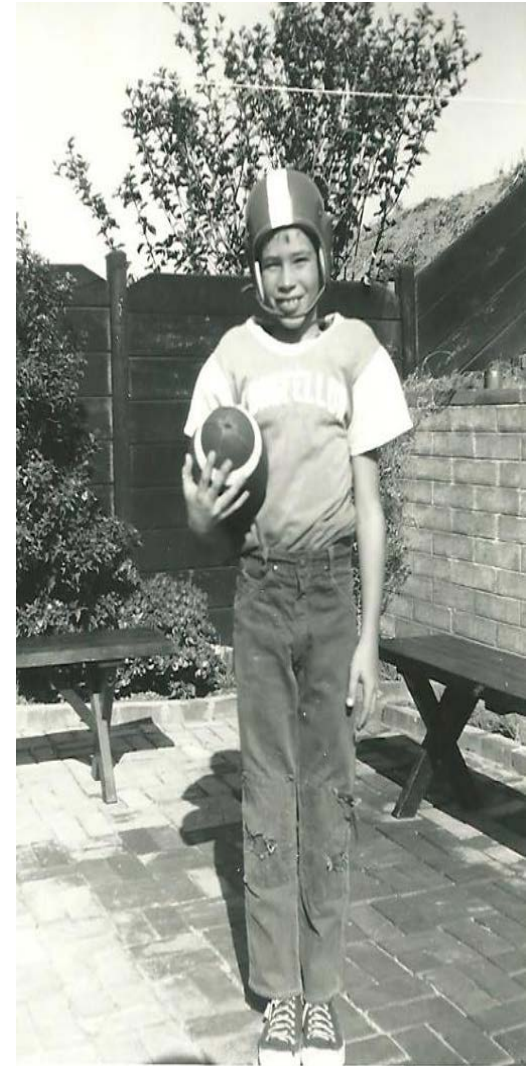
Partnering to Prevent Hypoglycemia

November 1, 2017

U.S. Department of Health and Human Services

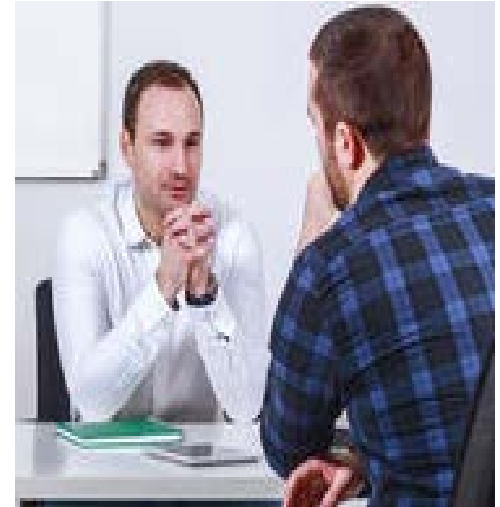
Why Should You Listen to Me?

- First of all, **Thank You** for inviting me to speak!
- This is a picture of me at about the time of my diagnosis, **age 10**. I was the only person (student, teacher, parent) with T1D anyone in my school knew at that time.
- In the 1970s, I had a summer internship at Eli Lilly and Co.
- I have survived many hypoglycemic events, both mild and severe, in the 57 years since this picture was taken.
- I have taken part in clinical trials to treat and cure type 1 diabetes, including being the first human to have beta cells implanted in my stomach lining through an endoscopic procedure at UCSF.
- I am a member of the Joslin Study of long-term survivors of T1D.



More Reasons to Listen

- I am a market researcher by profession. I listen to people and train my clients how to listen (LifeScan, Johnson & Johnson, Pfizer, Animas and others in the diabetes space, for example).
- With Lorraine, we have been active in diabetes circles for decades, in patient groups and research organizations. I have listened to the wants and needs of those with T1D.
- We have volunteered with dozens of diabetes charities and served on the boards of many.
- We have both written about our experiences living with T1D, and we have spoken extensively on this subject.



You have just a few things to think about as a person with T1D.

- How much insulin do I have in my body right now?
- How long will it act?
- What about stress, anxiety, adrenalin, illness?
- How much exercise have I had recently?
- What type of exercise was it and how and when will it affect me?
- How much food have I eaten? When?
- What types of carbohydrates have I eaten?
- How much fat and protein have I had and when?
- How quickly will the carbohydrates be absorbed?
- Where can I get access to more fast-acting carbs if I need them?
- I would prefer liquid carbohydrates, if possible, if I am worried about going low (gastroparesis).
- How much insulin is available in my pump?
- How long will it last? Do I have parts to add insulin?
- Do I have access to more? How quickly? How much? Where?
- How is my blood sugar trending? How quickly?
- How are the batteries in my pump and CGM?
- How are the injection sites for the pump and CGM? Any irritation, redness or infection?
- What is the age and condition of each piece of both devices? Are they adhering to my skin?
- Do I have access to syringes? Alcohol swabs?
- Do I have access to more pump supplies and more CGM sensors and transmitters? Where?
- **Even with due diligence and careful planning, my doctor estimates that someone like me could expect to have at least one severe hypoglycemic event per year.**

Why is preventing hypoglycemia so important?

- The one fear that all of us with T1D have **constantly**, the one that can dominate your life, is that we will die from not accurately gauging our exercise, food intake and absorption, and insulin action properly...resulting in a fatal hypoglycemic event, perhaps in our sleep.
- This fear is **ALWAYS** present, 24/7, no vacations, no days off. It is **ALWAYS** there for those who love and care about us as well.
- When I was diagnosed at age 10, my doctor told me “Live fast and loose, kid, because you won’t live to be 50.”



Hypoglycemic Events



What does hypoglycemia feel like?

- Symptoms are well-documented: shaking, sweating, inability to function physically, sleepiness, sometimes anger, inability to focus, numb lips, etc.
- The only way to describe the feeling is: **desperation for food**, anything sweet, fear of losing control and passing out, fear of dying.
- I have experienced such episodes in business presentations and meetings, on occasion (*like this one*).
- Preventing events like these would not only save embarrassment, but save lives as well.



Preventing Hypoglycemia

- **Continuous Glucose Monitors (CGMs)** are a godsend for people living with T1D!
- I cannot describe the confidence that comes from knowing that you have a device watching your blood sugars and letting you know not only where you are, but where you are headed.
- Even with the CGM, the patient needs to know about the threat of hypoglycemia in time to react.
- Studies have shown that patients who wear CGMs spend less time in hypoglycemic events and have fewer low blood sugars.



Preventing Hypoglycemia Through Patient Education and Training

- Patients often lose the ability to sense hypoglycemic events as they are progressing.
- The number (meter reading) does not always match how the patients feel. I have been coherent and rational at 38, and I have been symptomatic at 54.
- The recent patient history with blood sugars can strongly influence how the patient feels at different blood sugar readings.
- Each patient needs to learn what works for them in raising their blood sugar and how quickly it works. Deliberate experimentation can help with this strategy.



What do patients want?

- Prevent the threat to my life.
- Let me live without the constant worry of hypoglycemia.
- If you cannot cure me, at least give me the tools to survive.
(Remember slide #4, the list of questions to ask and remember as a person with T1D)
- Teach me how to predict and prevent hypoglycemic events.
- Teach me how to manage the risks of low and high blood sugars.



Thank You!



***Partnering to Maximize Physical and Emotional
Health
and Minimize and Prevent Hypoglycemia***

Paul B. Madden, M.Ed.

***Managing Director, Diabetes in Adults & Behavioral Health
American Diabetes Association***

Living a Bold Life with Type 1 Diabetes for 56 Years

Significant Contributions to this Presentation:

***Irl B. Hirsch, MD; Priscilla White, MD; Arturo Rolla, MD;
Leo Krall, MD; my family, diabetes specialists, primary care
providers, and hundreds of thousands of people living with
diabetes,***

I have worked with over the last 42+ years.

Challenges with Solutions

- NCDs are the major cause of new cases of poverty (WHO)
- Diabetes is the leading NCD in many countries; >30m in U.S. (CDC)
- >\$245B Diabetes expenses (2012 US)
- Unbalanced diabetes significantly diminishes productivity, quality and quantity of life.
- Unbalanced diabetes and new cases of diabetes increases health care costs for individuals, families, companies, schools, insurers, and taxpayers. Each of these groups represent some of our partners.
- INVESTMENT: Proper access to optimal interventions along with a healthy life style choices resulting in more balanced diabetes saves significant health care expenses and increases productivity, quality and quantity of life.

Symptoms of Hypoglycemia

Mild to Moderate to Severe

- Shaky or jittery
- Sweaty
- Hungry
- Headachy
- Blurred vision
- Sleepy or tired
- Dizzy; lightheaded
- Confused; disoriented
- Pale

- Uncoordinated
- Irritable or nervous
- Argumentative or combative
- Changed behavior or personality
- Trouble concentrating
- Weak
- Fast or irregular heart beat

- Unable to eat or drink
 - Seizures or convulsions (jerky movements)
 - Unconsciousness
- Some symptoms of hypoglycemia during sleep:
- crying out; having nightmares
 - Sweating excessively
 - tired, irritable; confused after waking up
 - DEAD in Bed (less healthy seniors and individuals)
 - Brain impairment in infants???

What Causes/Contributes to Hypoglycemia in diabetes?

- **If you take insulin or diabetes medicines that increase the amount of insulin your body makes—but don't match your medications with your food, physical activity, stress—you could develop hypoglycemia.** The following factors can make hypoglycemia more likely:
 - **Not eating enough carbohydrates (carbs) and calories**
 - **Skipping or delaying a meal**
 - **Increasing physical activity**
 - **Drinking too much alcohol without enough food**
 - **Being sick (too low or high blood sugars)**
 - **Forgetting if insulin/medicine was given earlier so given a second time.**
- Two types of diabetes pills can cause hypoglycemia: [sulfonylureas and meglitinides](#) .
- Although other diabetes medicines don't cause hypoglycemia by themselves, they can increase the chances of hypoglycemia if you also take insulin, a sulfonylurea, or a meglitinide.

Treating Hypoglycemia; Partners Play a Key Role

When hypoglycemia is treated early the solutions can be simple and down time minimized.

Examples include:

- 2-4 [glucose tablets](#) or one tube of [glucose gel](#)
- 1/2 cup (4 ounces) of fruit juice—not low-calorie or reduced sugar
- 1/2 can (4 to 6 ounces) of soda—not low-calorie or reduced sugar
- 1 tablespoon of sugar, honey, or corn syrup, 2 tablespoons of raisins

When not treated early the accompanying complications can be serious even tragic leading to unconsciousness (dead in bed, driving, working while on a ladder or on a roof, etc.

Are these solutions readily available in the workplace, in our schools, etc.?

How I + WE Prevent Hypoglycemia/Adverse Events

- **ENSURE PROPER ACCESS AS PRESCRIBED BY PATIENT'S HEALTH CARE PROVIDER**
- **Remove restrictions on obtaining blood strips/CGMS. Focus on CGMS for a growing number of people especially but not restricted to just the 1.5m with type 1 and the approx. 6.5m type 2s taking insulin.**
- **Base Access on the Research: Studies are increasingly demonstrating that CGM use is decreasing time in hypoglycemia.**
- **Have foods including glucose readily available.**
- **Be physically active safely. (home, school, workplace)**
- **Work with MY health care team**

I = WE = DSME approach with PLWD

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Are these solutions readily available in the workplace, in our schools, etc.?

Growing Opportunities to Minimize Hypoglycemia + Other Complications with Today's Rapid Advances

- **Unparalleled advances in diabetes related medicines (SGLT1, SGLT2, new insulins, and technologies (CGMS, hybrid insulin pumps, insulin pen smart caps, sharing blood sugar levels with others, etc.) are significantly improving opportunities for diabetes and cardiovascular health, improved quality of lives and safety, increased productivity and reduction of health care costs throughout a lifetime benefitting individuals, families, businesses, schools, and taxpayers.**
- **Including more people living with diabetes in this important dialogue.**
- **These advances are improving the quality, quantity and safety of lives for people with diabetes. Thank you.**

Understanding People Remember

- 20% of what they see*
- 30% of what they hear*
- 50% of what they see and hear*
- 80% of what they see, hear and do. This is fostering empowerment!*
- Proper engagement ensures development of most effective, usable clinical interventions.

* Prof. Fred Hofsteter, Director, Instructional Technology Center, University of Delaware, US.

Optimizing Interventions by Engaging People Living with Diabetes

- **INVESTMENT** – Change approach so that we look at unbalanced diabetes which significantly diminishes productivity and quality of life outcomes as an opportunity to properly invest in the diabetes consumers' needs and health to optimize diabetes management and health and life outcomes.
- Knowledgeable people living with diabetes do help ensure proper development of medicines and technologies that address their needs to improve diabetes management, health and life outcomes.

Unparalleled Advances in Diabetes

"There are only two ways to live your life.

One is as though nothing is a miracle.

The other is as though everything is a miracle."

Albert Einstein

As we get closer to more absolute, safer balance of blood sugar levels, significantly decreasing the costly complications that most times do NOT have to accompany diabetes and eventually the cures and preventions, we are approaching close to miracle interventions that will improve our lives closer to not having diabetes. Thank you.

Working Together to Improve Lives of People with Diabetes

People Living with Diabetes and their loved ones.

Colleagues and Associations focused on DM Care

NIH, NIDDK, FDA, Employers, Schools, etc.

American Diabetes Standards of Medical Care

We invite your suggestions on best research and clinical experiences and opportunities that will benefit this important focus to

**improve the lives of
people living with diabetes.**

**Thank you from the bottom of
my pancreas,
Which is like the bottom of my
heart,**

**ONLY DEEPER!
Paul B. Madden, M.Ed.**

Living a Bold Life with Diabetes for 56 Yrs.

American Diabetes Association

AHRQ's SHARE Approach to Shared Decision Making

Alaina Fournier, PhD

Division of Practice Improvement

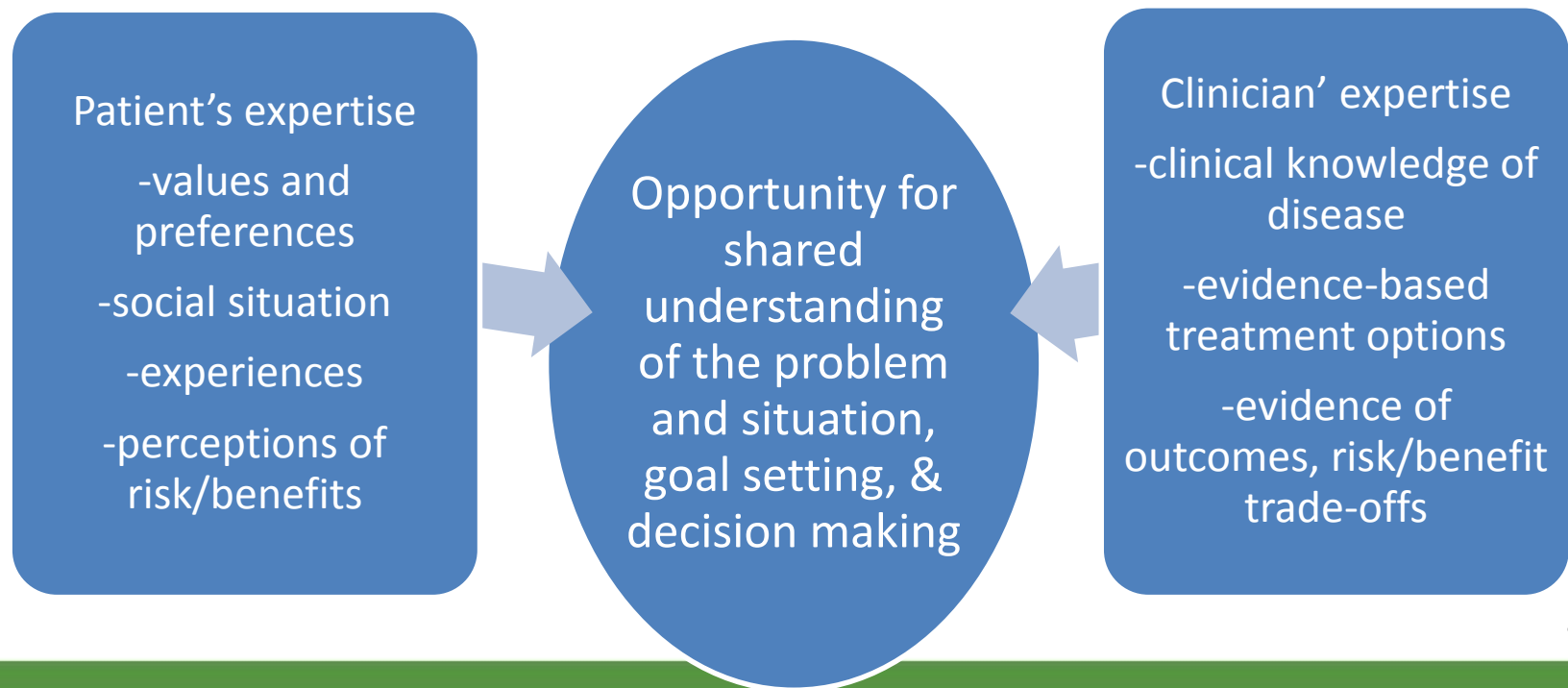
Center for Evidence and Practice Improvement

Agency for Healthcare Research and Quality



What is shared decision making?

- ▶ **Shared decision making** occurs when a health care provider and a patient work together to make a health care decision that is best for the patient.



Why do shared decision making?

- ▶ Recognized as good clinical practice for providing patient-centered care.¹
- ▶ Patients want to be involved.²⁻³
- ▶ Improves patient satisfaction and experience of care.⁴
- ▶ May improve health outcomes for patients.⁵⁻⁸
- ▶ National policy and quality improvement initiatives promote shared decision making.⁹



AHRQ's SHARE Approach to shared decision making - development

Goal: Support the use of evidence to inform decision making between health professionals and patients by creating a training workshop curriculum for clinicians.

- ▶ Conducted formative research to understand clinicians' training needs:
 - How to engage patients in the SDM process and elicit preferences
 - Approaches that can be used in a limited time context/finding time
 - Cultural competency
 - Communicating technical information about conditions and options
 - Communicating harms/benefits, risk communication competencies
 - How to find appropriate evidence-based decision aids

The **SHARE** Approach

Essential Steps of Shared Decision Making

Five steps for you and your patients to work together to make the best possible health care decisions.

Step 1:

Seek your patient's participation

Communicate that a choice exists and invite your patient to be involved in decisions.

Step 2:

Help your patient explore and compare treatment options

Discuss the benefits and harms of each option.

Step 3:

Assess your patient's values and preferences

Take into account what matters most to your patient.

Step 4:

Reach a decision with your patient

Decide together on the best option and arrange for a followup appointment.

Step 5:

Evaluate your patient's decision

Plan to revisit decision and monitor its implementation.



Agency for Healthcare Research and Quality
Advancing Excellence in Health Care • www.ahrq.gov



Effective Health Care Program

www.ahrq.gov/shareddecisionmaking

April 2014 AHRQ Pub. No. 14-0026-2-EF

SHARE Approach Training Curriculum



Module 1: Shared Decision Making using the SHARE Approach

Module 2: AHRQ PCOR Resources: What's available, where to find them, how to use them

Module 3: Communication: Common communication barriers to shared decision making – health literacy and numeracy, cultural competency, using teach-back

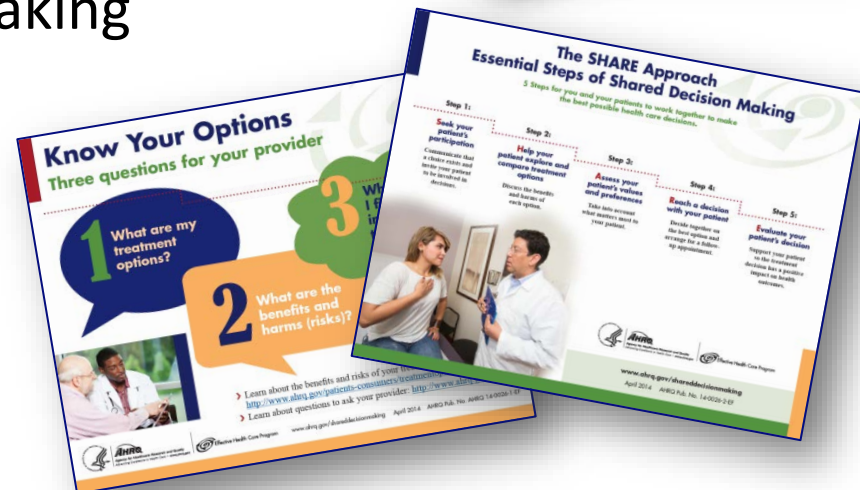
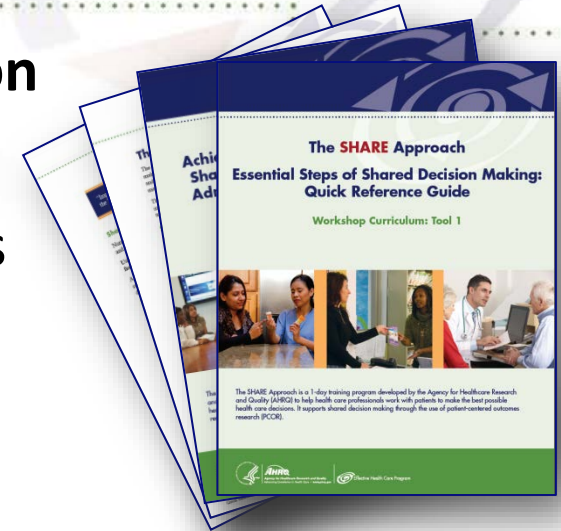
Module 4: Putting SDM Into Practice: Using a team-based approach to implement shared decision making

Trainer's Module

The SHARE Approach Tools

► Shared Decision Making and Communication Tools

- Describe the SHARE Approach - includes conversation starters, a video, and posters
- Address common communication barriers to shared decision making
- Help gain buy-in and implement shared decision making in practice



Who is involved in shared decision making in the clinical setting?



The entire medical team should be familiar with and involved in shared decision making.

Collaborative roles in shared decision making – Key Roles

▶ Patient

- Actively participates and is the center of shared decision making

▶ Physician, physician assistant, or nurse practitioner

- Lets their patient know there is a choice and invites patient to be involved in the decision
- Presents options and describes the risks and harms
- Explores patient's values and preference

Collaborative roles in shared decision making – other team members

- ▶ Decision coach (nurses, social workers, health educator)
- ▶ Shared decision making manager/support staff
- ▶ Medical treatment specialists
- ▶ Family members and caregivers



What does decision conflict look like?

Your patient may:

- Verbalize uncertainty about the choice
- Waver between choices
- Delay the decision
- Question personal values or what is important to them
- Be preoccupied with the decision
- Show signs of distress or tension

So why isn't shared decision making happening?

► Attitudinal Barriers

- “I’m already doing it”
- Concerns about lack of time
- Lack of skills
- Lack of resources at the clinical level
- Concerns about patients’ ability to make appropriate choices



► Organizational Barriers

- Lack of leadership
- Lack of resources for training, decision aids, infrastructure
- Lack of measures for success

Advancing shared decision making



- ▶ Building an SDM culture
- ▶ Training participants in SDM skills
- ▶ Infrastructure to support SDM
- ▶ Patient decision aids
 - Developing and updating continually
 - Integration into EHRs
- ▶ Research to better understand how to implement SDM at the practice and organizational levels
- ▶ Better measures to evaluate shared decision making in practice



Thank you!

Alaina Fournier

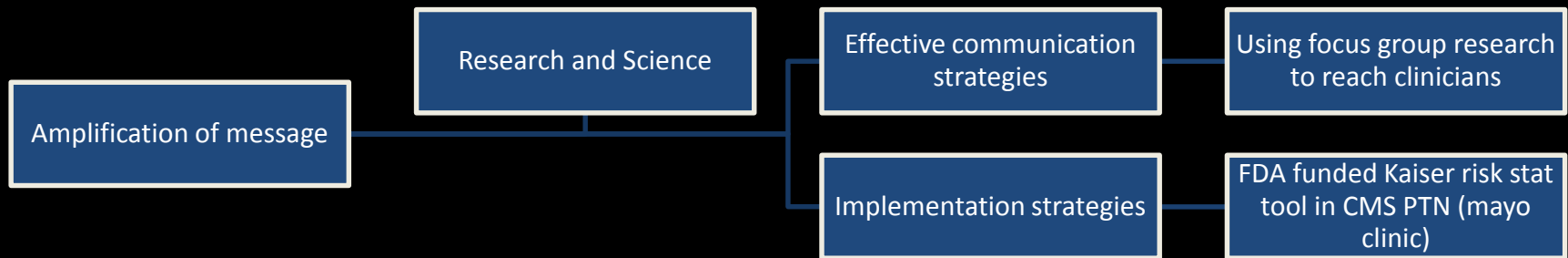
Agency for Healthcare Research and Quality

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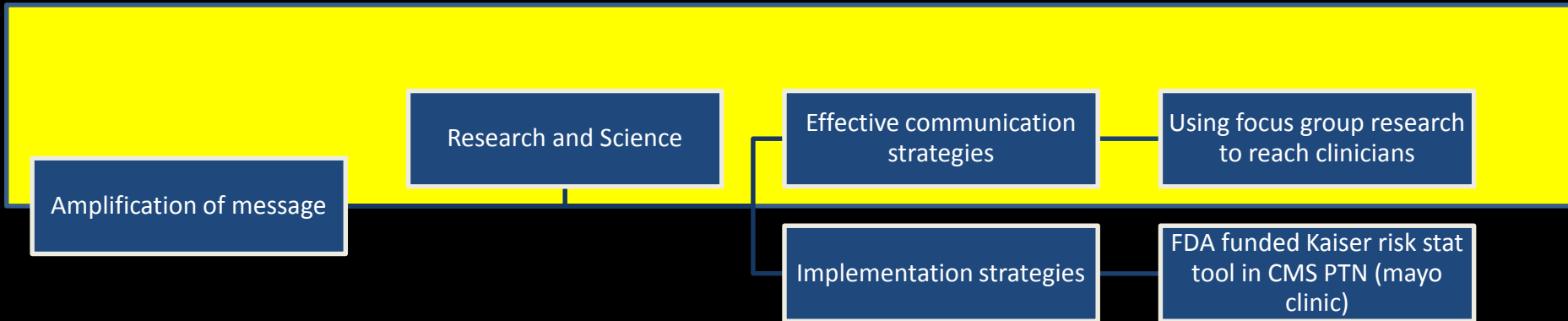
Driving amplification of message using research and science

John Whyte MD MPH
Professional Affairs and Stakeholder
Engagement

Driving amplification of message using research and science



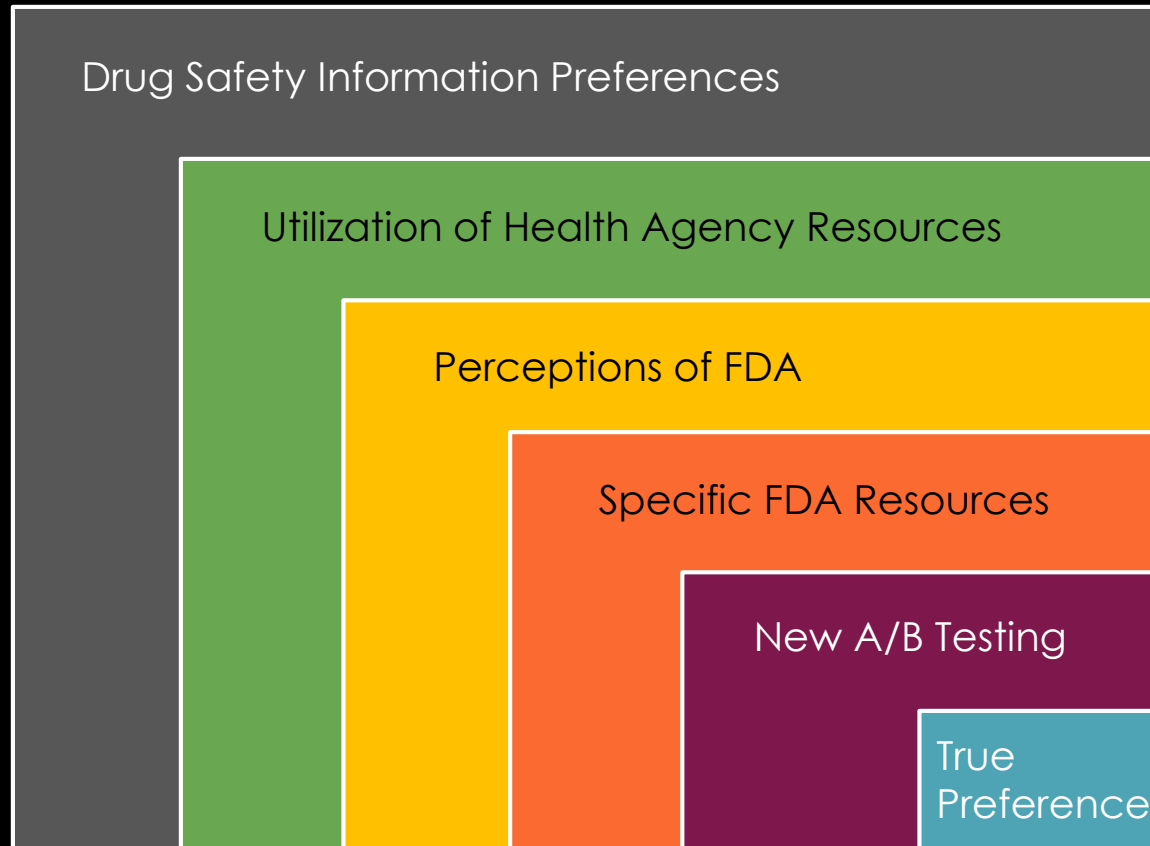
Effective communication strategies



Focus Group Design

Hypothesis:

Physicians do not use FDA as a primary resource for drug safety



“...I hate to say it, but I Google it too...”

“I use Google and Micromedex. Medscape sometimes...”

“...WebMD or I find out through emails from my society”

“Usually the specialty bodies...”

“The pharmacist that rounds with me and Specialty society”

“...I Google and UpToDate....”

“Epocrates is another option I tend to use...”

“Google primarily, Specialty Societies, and Lexicomp ...”

What is your Primary Source
for Drug Safety Information?

“...I hate to say it, but I Google it too...”

“I use Google and Micromedex. Medscape sometimes...”

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Google

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“The pharmacist that rounds with me and Specialty society”

“...I Google and UpToDate...”

“Epocrates is another option I tend to use...”

“Google primarily, Specialty Societies, and Lexicomp ...”

Third Party Apps

“...I hate to say it, but I Google it too...”

“I use Google and Micromedex. Medscape sometimes...”

“...WebMD or I find out through emails from my society”

“Usually the specialty bodies...”

“The pharmacist that rounds with me and Specialty society”

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Physician Web Resources

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“Google primarily, Specialty Societies, and Lexicomp ...”

Professional Organizations

“

I don't know honestly what the resources directly from the FDA are.

”

Pediatrician (42), Chicago

“

You know it has never occurred to me to go to the FDA to look up for anything.

”

Pain Medicine Physician (46), Boston

IN THEIR OWN WORDS

**General
lack of
awareness
of FDA
resources**

Labyrinth to Navigate Ineffective Gatekeeper Regulatory
Not Timely Difficult to Work Minimal Standards Cautious
Trustworthy Not useful Search through Data Political agenda
Drug Studies Regulate doctors Trustworthiness Frustrations
Appreciative Skeptical of Biases Busy for Government Trust
Illogical Under Funded Drug Regulations Gold Standard
Frustrated Inconvenient Patient Package Insert Off-label
Regulatory Public Health Inconvenient Bureaucratic Good
Labeling Black Box Frustrating Road Block Drug Review
Pass too many drugs Ambivalence Verified and Safe Bad

What is your perception
of the FDA?

//

...the FDA website is worst
of all, of any website, it's
almost like invented to be
complicated...

Rheumatologist (63), Boston

//

IN THEIR OWN WORDS

FDA
materials
are difficult
to find

//

It's like really small print...
and the older you get the
more difficult that is. I think
anything that you have to
fold up 20 times... that's not
good.

Cardiologist (37), Nashville

//

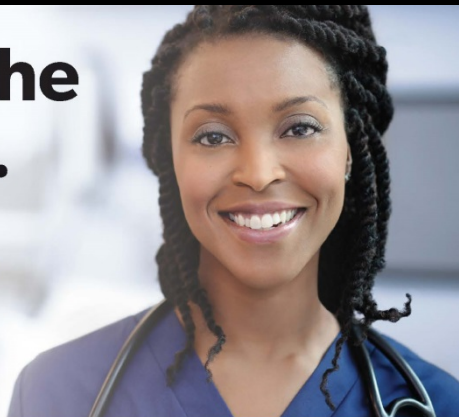
IN THEIR OWN WORDS

Drug Label is not user friendly

Get the facts.

23%

of adult Internet consumers surveyed report that they have bought prescription medicine online.*



GET A PRESCRIPTION



KNOW YOUR ONLINE PHARMACY



ONLY BUY FROM A SAFE, LEGAL PHARMACY



TAKE MEDICINE AS DIRECTED

Buying from fraudulent online pharmacies can harm your patients.

According to the National Association of Boards of Pharmacy, only 3 percent of more than 10,000 online pharmacies reviewed comply with U.S. pharmacy laws. Many rogue online pharmacies use fake "storefronts" to make people think they come from countries with high safety standards.

If a drug does not have the desired effect, ask where your patient got his or her prescription filled.

Use of counterfeit and substandard drugs can result in adverse reactions, drug interactions, or other contraindications. These effects may be mistakenly attributed to other causes, or may mask other symptoms.

Send your patients to www.FDA.gov/BeSafeRx.

FDA BeSafeRx is a public health campaign to help protect patients from fraudulent online pharmacies. The website includes warning signs of fraudulent online pharmacies and tips for buying medicine safely online. The site also has ready-to-print resources for you to share with your patients.



FDA

BeSafeRx
Know Your Online Pharmacy

* FDA conducted a survey through an online panel in the U.S. comprised of adults aged 18 years and older, who have purchased products using the Internet and opted in to complete this survey. This survey is not representative of the general population.

GET THE FACTS



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Note to Physicians

Do not put your patients, yourself or your practice at risk by purchasing and administering unapproved foreign-sourced drugs.

Most of the drugs from foreign sources have not been approved by the Food and Drug Administration (FDA) and may include misbranded, adulterated and counterfeit versions of FDA-approved drugs. They may not be of suitable quality to ensure safety or efficacy.

The FDA is concerned that these unapproved foreign drugs may cause harm or not properly treat your patients, because they may be unsafe or ineffective.

If you buy or use foreign-sourced drugs that are not FDA approved, you may find yourself to be the subject of a criminal investigation by the FDA's Office of Criminal Investigations, FBI, and ICE's, Homeland Security Investigations. Do not run the risk of your patients receiving ineffective medication or you or your practice becoming subject to criminal and/or civil penalties and administrative sanctions.

Tips: Be sure to look at the labels of the drugs you receive. The lot number on the drug label should match the lot number on any outer packaging. By law, the label must be in the English language and bear the words "Rx Only." Virtually all approved prescription drug labels also bear the National Drug Code (NDC) number used in connection with billings to Medicare and other government health care benefit programs. Beware of call centers located abroad and prices that sound too good to be true. Only buy from a state-licensed wholesale drug distributor or directly from the manufacturer.

For more information, visit:
<http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm299920.htm>

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U.S. Food and Drug Administration
Protecting and Promoting Your Health

For more information, visit: <http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm299920.htm>

FDA Drug Safety Communication: FDA cautions about using testosterone products for low testosterone due to aging; requires labeling change to inform of possible increased risk of heart attack and stroke with use

This information is an update to the FDA Drug Safety Communication: FDA Evaluating Risk of Stroke, Heart Attack, and Death with FDA-Approved Testosterone Products issued on [January 31, 2014](#).

Safety Announcement

[03-03-2015] The U.S. Food and Drug Administration (FDA) cautions that prescription testosterone products are approved only for men who have low testosterone levels caused by certain medical conditions. The benefit and safety of these medications have not been established for the treatment of low testosterone levels due to aging, even if a man's symptoms seem related to low testosterone. We are requiring that the manufacturers of all approved prescription testosterone products change their labeling to clarify the approved uses of these medications. We are also requiring these manufacturers to add information to the labeling about a possible increased risk of heart attacks and strokes in patients taking testosterone. Health care professionals should prescribe testosterone therapy only for men with low testosterone levels caused by certain medical conditions and confirmed by laboratory tests.

Testosterone is FDA-approved as replacement therapy only for men who have low testosterone levels due to disorders of the testicles, pituitary gland, or brain that cause a condition called hypogonadism. Examples of these disorders include failure of the testicles to produce testosterone because of genetic problems, or damage from chemotherapy or infection. However, FDA has become aware that testosterone is being used extensively in attempts to relieve symptoms in men who have low testosterone for no apparent reason other than aging. The benefits and safety of this use have not been established.

In addition, based on the available evidence from published studies and expert input from an [Advisory Committee meeting](#), FDA has concluded that there is a possible increased cardiovascular risk associated with testosterone use. These studies included aging men treated with testosterone. Some studies reported an increased risk of heart attack, stroke, or death associated with testosterone treatment, while others did not.

Based on our findings, we are requiring labeling changes for all prescription testosterone products to reflect the possible increased risk of heart attacks and strokes associated with testosterone use. Health care professionals should make patients aware of this possible risk when deciding whether to start or continue a patient on testosterone therapy. We are

//

See, it's way too long, it's not specific enough, it gives nothing that's really useful because it's very complete...but a busy clinician is not going to read five pages of data.

Rheumatologist (63), Boston

//

IN THEIR OWN WORDS

**DSCs too
long and
nonspecific**

//

..I was overwhelmed with how to report a side effect and I just learned something tonight. I was expecting to fill out 50 pages of paper and if I can go online and click a couple things and get it started I would like to report it...

Family Practice (51), Washington D.C

//

IN THEIR OWN WORDS

**Interaction
with FDA is
perceived as
frustrating**

//

I knew I only had to listen to five points and I survived, so even at point three and four I was like woo-hoo we're almost there. I felt like I learned something from it.

Surgical Critical Care Specialist (34), Omaha

//

IN THEIR OWN WORDS

**Doctors
prefer a
roadmap for
decision
making**

Focus Group Lessons

1. Physicians are either unaware of FDA resources or find the experience frustrating and give-up
2. Physicians rely on others for easier to access concise drug safety information
3. Physicians prefer content targeted to their specialty

Translation of findings to drive amplification of message

Physicians prefer content targeted to their specialty

Collaboration with American Geriatric society , ADA, Endocrine Society to AMPLIFY the message

Twitter chat for Diabetes month on hypoglycemia


Key messages/ infographic on hypoglycemia for clinicians

Publications (E.g. Endocrine society magazine

FDA hypoglycemia workshop (Sept 12, 2017)



Medscape article




FDA Public Workshop

Reducing the Risk of Preventable Adverse Drug Events Associated with Hypoglycemia in the Older Population

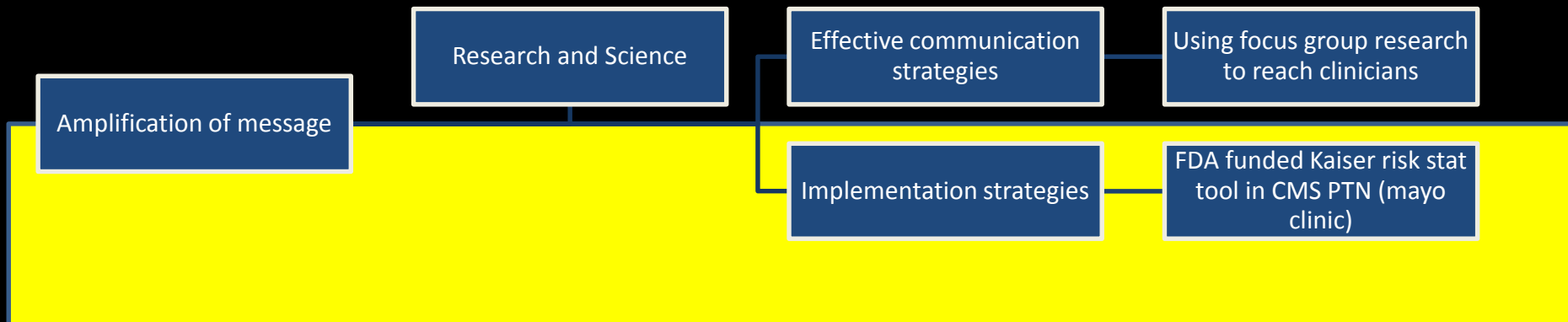
September 12, 2017
8:00am - 4:30pm
WO Building 31, Room 1503

Hosted By:
Professional Affairs and Stakeholder Engagement (PASE)
Safe Use Initiative

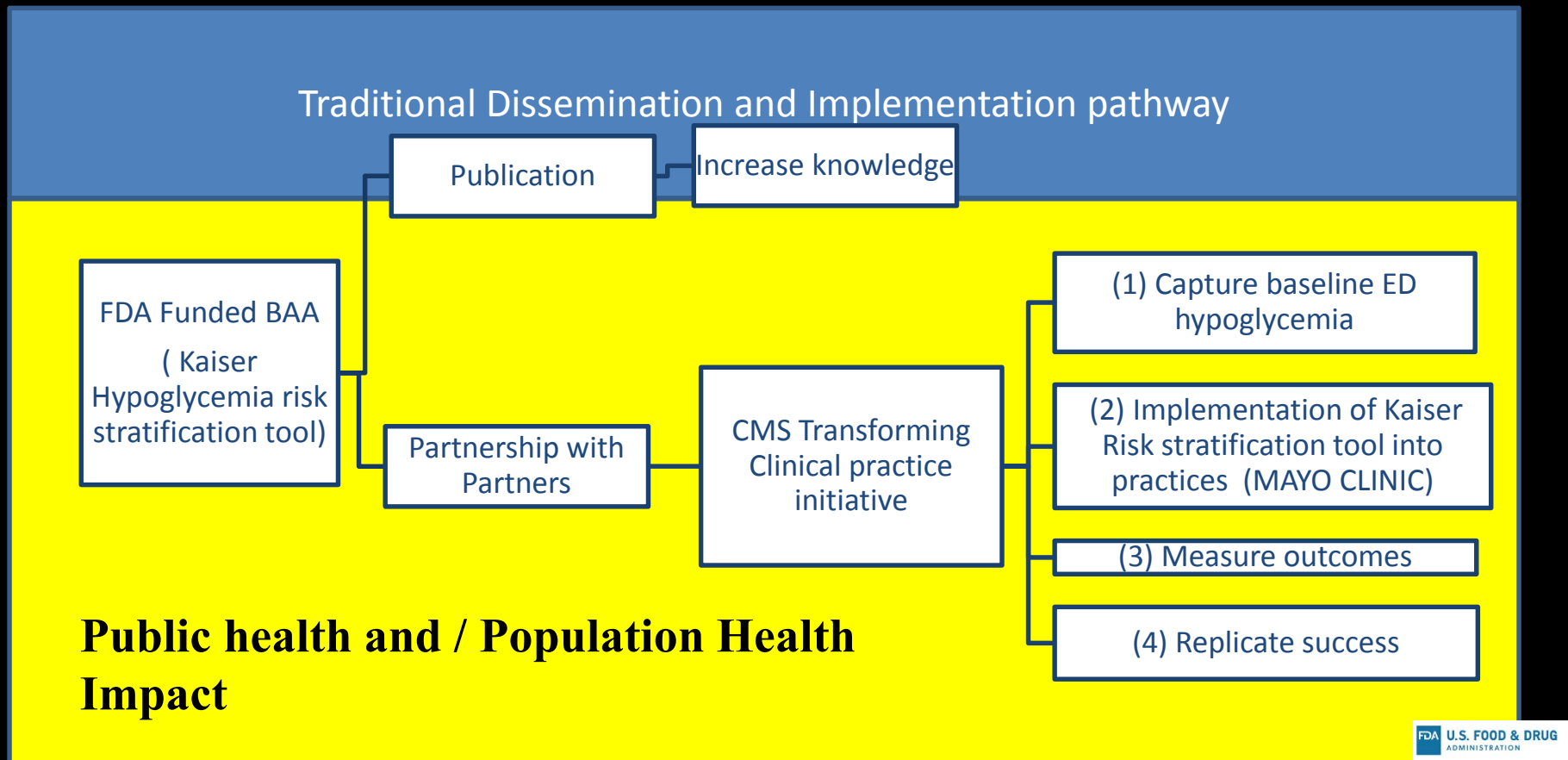


Keynote Speaker:
Don Wright,
MD, MPH
Acting Assistant
Secretary for Health HHS
Office of the Secretary

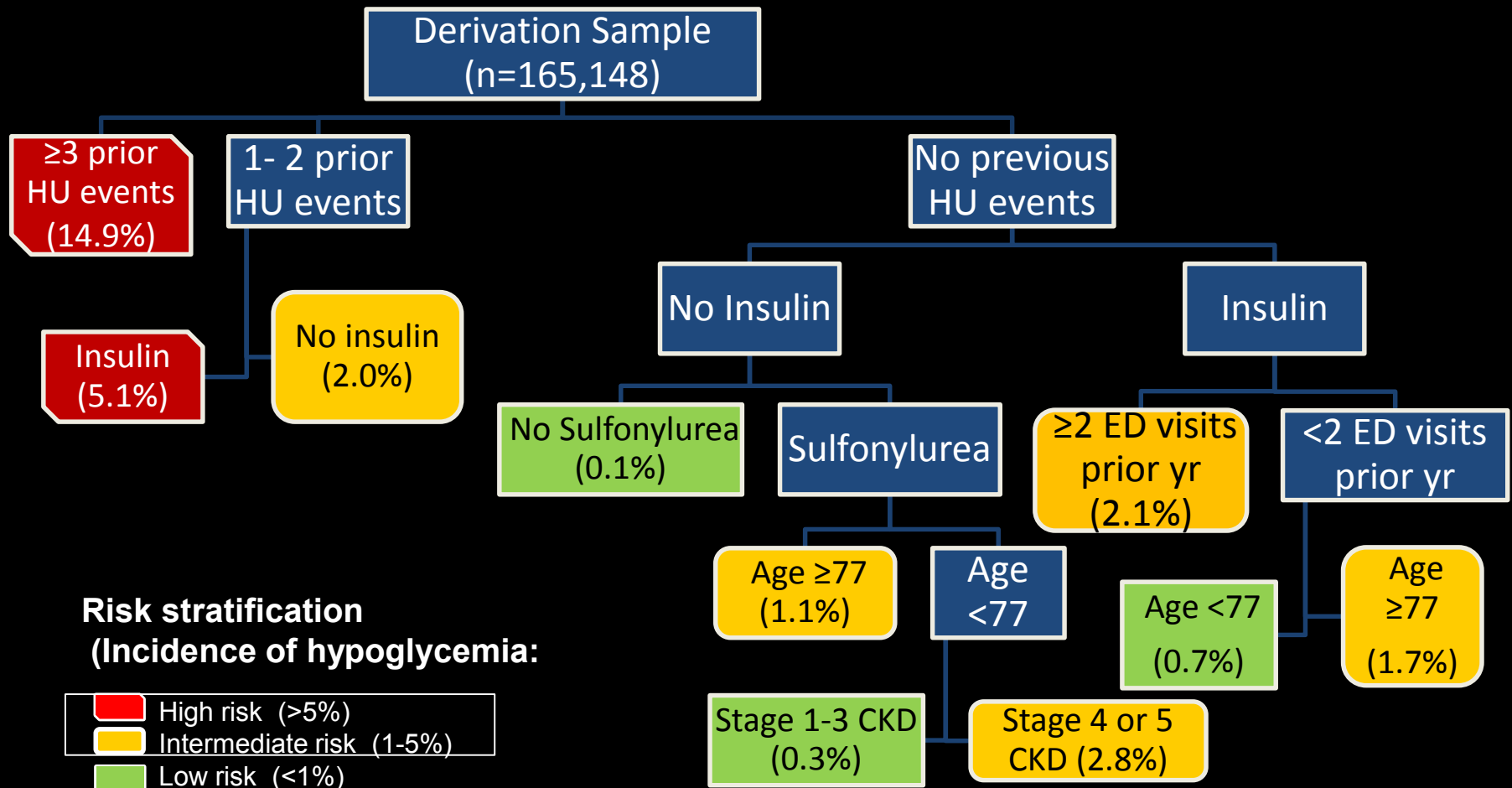
Implementation strategies



Implementation of research into practice: Hypoglycemia Storyline of Collaboration



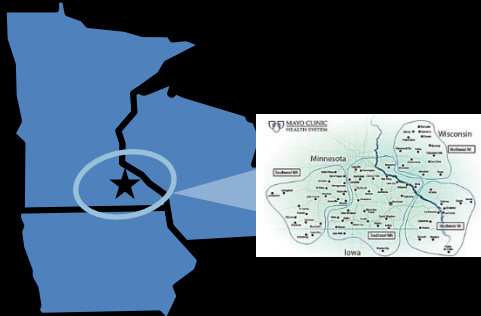
Classification Tree



*Based on 156 candidate variables linked to 808 HU events (any primary diagnosis in ED or principal diagnosis in hospital for hypoglycemia) occurring in 165,148 T2D adults from Kaiser Permanente (4.9 events per 1000 person years) in 2014; HU risk for each leaf node (solid boxes) in parentheses.

Overview – Mayo PTN

MAYO CLINIC in the MIDWEST



Academic Medical Center Rochester, Minn.

- 500,000 patients/year
 - 2,000 physicians
 - 125 primary care providers
 - Primary care
 - At full risk for PC
- GE EMR*

Community and Regional Health System 75 communities in Minn., Iowa and Wis.

- 4 regions
 - 18 hospitals
 - 525,000 patients/year
 - 1,000+ physicians
 - Primary care
 - At risk for PC
- Cerner EMR*

MAYO CLINIC in the SOUTHWEST



Arizona

- 90,000 patients/year
- Approx. 400 physicians
- Primary care
- At full risk for PC

MAYO CLINIC in the SOUTHEAST



Florida

- 90,000 patients/year
- Approx. 400 physicians
- Primary care
- At full risk for PC

Separate Cerner EMR

Implementing the Hypoglycemia Risk Prediction Tool

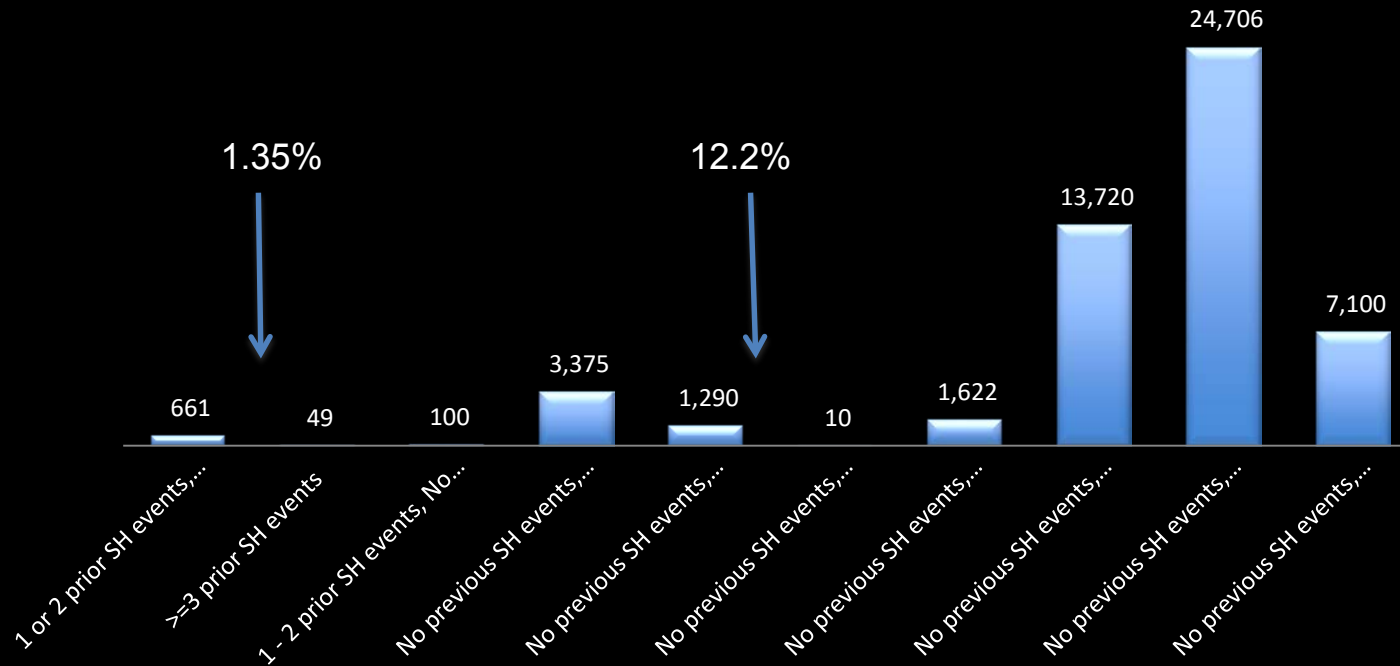
90 primary care clinics – Mayo
Clinic PTN

Patients attributed to clinicians,
care teams and clinics

Patients identified with a diagnosis
of type 2 diabetes – n= 52,633

Implement risk prediction tool

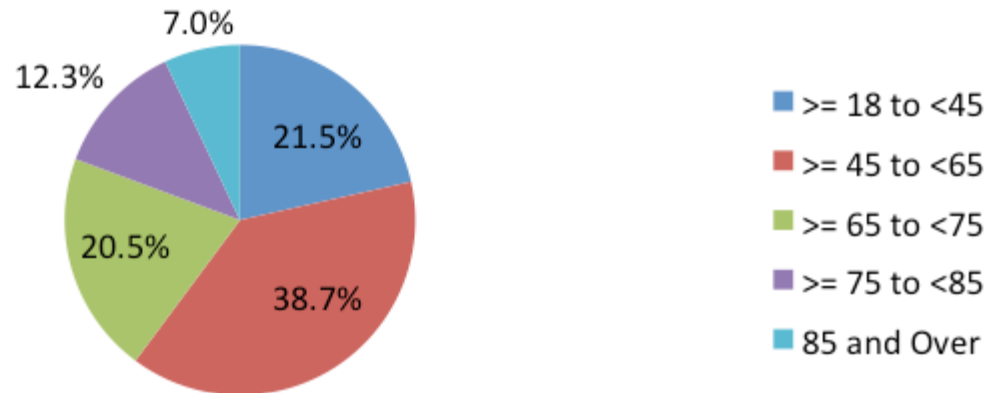
Hypoglycemia Risk across Mayo Clinic PTN



Risk of Hypoglycemia by Age

| Risk Group | Age (mean) | Range |
|------------------------|-------------|--------|
| High (n=698) | 59.2 (17.7) | 18-99 |
| Intermediate (n=6,281) | 79.9 (10.7) | 18-104 |
| Low (n=45,637) | 63.5 (13.4) | 18-87 |

Age Group Distribution of High Risk Group



Summary

- Implementation of hypoglycemia risk prediction tool is feasible
- Significant variation in risk across clinics and care teams
- Pilot low-cost approaches may decrease risk, improve health outcomes, and decrease preventable utilization
- Potential benefit from collecting self-reported risk of hypoglycemia

Take away points

- Utilizing research and science key to
 - Effectively communicating with clinicians, especially in an oversaturated communication world
 - Moving research into practice

Additional slides



| Demographics | Characteristics | |
|-----------------|------------------|----|
| Gender | Male | 39 |
| | Female | 29 |
| Race /Ethnicity | Caucasian | 32 |
| | Asian | 13 |
| | African American | 16 |
| | Hispanic | 7 |
| | Other | 0 |
| Age | <30 | 1 |
| | 30-39 | 15 |
| | 40-49 | 25 |
| | 50-59 | 15 |
| | >60 | 12 |



| Physician | Specialty | |
|-----------|------------------------|----|
| | Pediatrics | 7 |
| | Allergy | 3 |
| | Neurology | 3 |
| | Cardiology | 5 |
| | Emergency Medicine | 3 |
| | Infertility | 2 |
| | Oncology | 2 |
| | Ophthalmology | 3 |
| | Radiology | 2 |
| | Anesthesiology | 3 |
| | Surgical Critical Care | 1 |
| | Internal Medicine | 15 |
| | Pulmonology | 5 |
| | Psychiatry | 1 |
| | Rheumatology | 2 |
| | Pain Medicine | 3 |
| | OBGYN | 1 |
| | Podiatry | 1 |
| | Physical Medicine | 3 |
| | Urology | 1 |
| | Orthopedics | 1 |
| | Family Medicine | 1 |



VHA Choosing Wisely – Hypoglycemia Safety Initiative

Speaker:

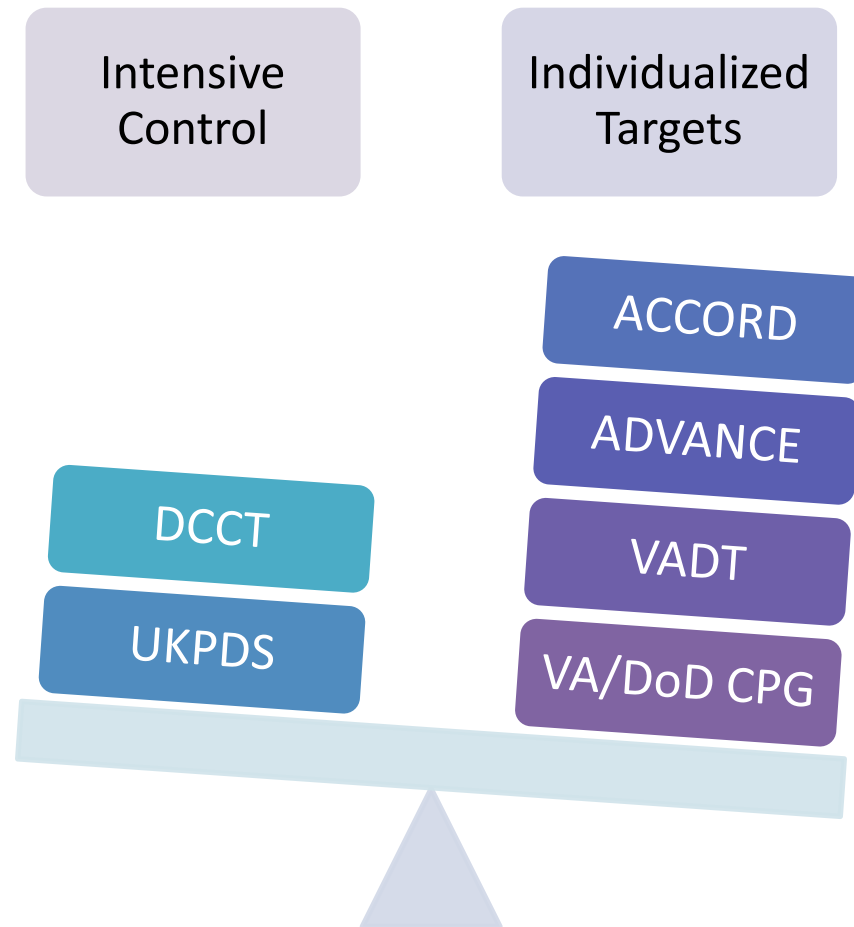
Sandra C. Hedin, PharmD, BCACP
Initiative Co-Lead

Supported by the VHA Choosing Wisely Task Force

Chartered May 2014

Under the auspices of Dr. Leonard Pogach (Specialty Care)

The Evidence



VHA Choosing Wisely: Hypoglycemia Safety Initiative (HSI) Goals



Foster Shared Decision Making

Inform Best Available Evidence

Reduce Unnecessary Care

Improve Safety

VHA HSI Support:

- VA/DoD Guidelines 2010 & 2017
- HHS National Action Plan for Adverse Drug Event Prevention (2014)
- CMS Quality Measure Development Plan (2016)

High Risk Populations

Intensive glucose
control / A1C
targets

Advanced age
and/or cognitive
decline

Low health literacy
and numeracy

Social determinants
including food
insecurity

Insulin and/or
sulfonylurea
medication therapy

Low economic
status

Prior hypoglycemic
event

Hypoglycemia
unawareness

Liver / kidney
disease

Implementation

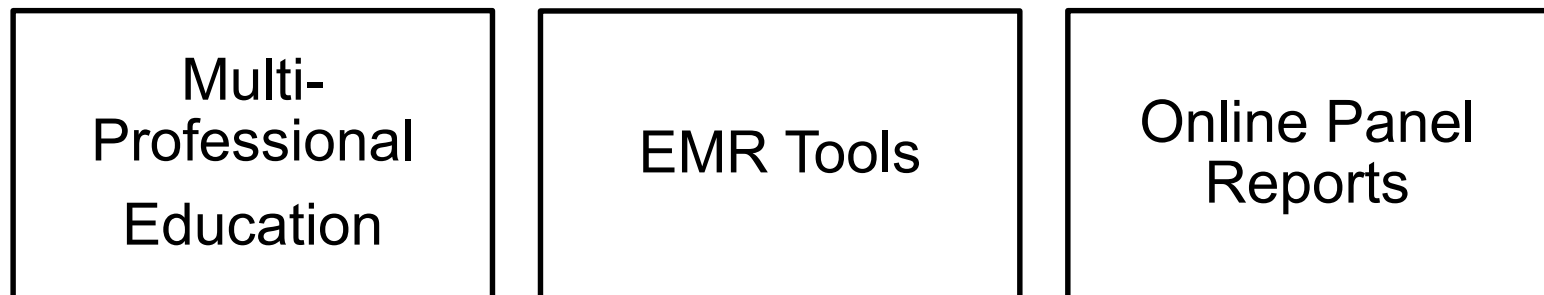
- Identify a specific, manageable cohort of patients at risk for hypoglycemia who may be overtreated utilizing EMR tools
- Provide patients and providers with resources & education on all key messages

Identification of Patients – EMR tools

High risk cohort


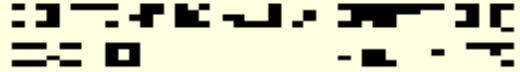





Integrated Approach



EMR Tools, cont.

Clinical Alert - Point-of-care patient identification

| | | | |
|---|-------------|---|---|
|   | | Visit Not Selected Provider:   |  |
| Active Problems Gastroesophageal Reflux Disease (SCT 55822004) Hyperlipidemia (SCT 55822004) Type 2 Diabetes Mellitus Without Compl Chronic Atrial Fibrillation (SCT 42674900 Visual Impairment (SCT 397540003) | | Allergies / Adverse Reactions Simvastatin Niacin [Niaspan Starter Pack] Colestipol | |
| Active Medications | | Clinical Reminders | |
| Precision Xtra (glucose) 50 Test Strip | Active/Susp | *** HOW TO RESOLVE A REMINDER *** | DUE NOW |
| Fluticasone Prop 50mcg 120d Nasal Inhl | Active | ~~~~~ | DUE NOW |
| Lancet, Lite Touch | Active | D: Advance Directive | DUE NOW |
| Insulin, Glargine 100 Unt/MI 3ml Solostar | Active | PRM PharmD, Pharmacotherapy Rem 1/7 | DUE NOW |
| Needle, Pen 31g, 8mm | Active | D: Diabetes Hypoglycemia Screen | DUE NOW |
| Non-Va Ranitidine Hcl 150mg Tab | Active | D: ID Screen/Prevnar 13 | DUE NOW |
| Non-Va Diltiazem (tiazac) 180mg Sa Cap | Active | D: Prevention - Non VA Meds | Oct 10, 16 |
| Non-Va Rosuvastatin Ca 20mg Tab | Active | ~~~~~ | DUE NOW |
| Non-Va Multivitamins Cap/Tab | Active | N: Braden Scale(OPT/Non Acute) | Jun 23, 16 |
| Non-Va Metformin Hcl 1000mg Tab | Active | N: ID Screen/Influenza (Off Season) | DUE NOW |
| Non-Va Warfarin (coumadin) Na 4mg Tab | Active | ~~~~~ | DUE NOW |
| Non-Va Insulin Glargine Solostar Inj | Active | | |
| Non-Va Tamsulosin Hcl 0.4mg Cap | Active | | |

EMR tools, cont.

1. Questions

2. Care Plan

3. Data Capture

Reminder Dialog Template: Hypoglycemia Screen

Screening for hypoglycemia should be performed in patients at risk for hypoglycemia. Studies show an increased risk for hypoglycemia in patients on insulin and/or a sulfonylurea with a recent A1C less than 7 and who:

- Are over the age of 74 or
- Have a diagnosis of cognitive impairment or dementia or
- Have a recent serum creatinine value greater than 1.7

Screening for hypoglycemia is indicated at least every 6 months for patients at risk.

[INSERT HEMOGLOBIN A1C OBJECT HERE]

☒ Perform Hypoglycemia Screening

In the past few months, how often did the patient/caregiver report that the patient had a low blood sugar?

☐ None reported
☒ Once

In the past few months, how often did the patient/caregiver report that the patient had a low blood sugar serious enough that the patient felt they might pass out?

☐ None reported
☐ Once
☒ 2-3 times per month

Did the patient/caregiver report that the patient passed out or fell because of a low blood sugar?

☐ No
☒ Yes Comment: _____

☐ Once a week
☐ Daily

Did the patient/caregiver report that the patient required a visit to a clinic/Emergency Dept/hospital because of a low blood sugar?

☐ No
☒ Yes Comment: _____

☐ 2-3 times per month
☐ Once a week
☐ Daily

Shared Patient Centered Plan

☐ No change in glycemic management at this time.
☒ Relax glycemic treatment Comment: _____

Visit Info Finish Cancel

Hypoglycemia Screen:
In the past few months, how often did the patient/caregiver report that
Health Factors: FAINTNESS (2-3 PER MONTH), HYPOGLYCEMIA (ONCE), HYPOGLYCEMIC MANAGEMENT-RELAX, HYPOGLYCEMIC RELATED VISIT (YES), PASS
T/FALL - YES

Online Panel Reports

Proactive Patient Identification

| Patient Name | HLA | Age | Dementia Cog Impair | SCR > 1.7 | HbA1c Value | HbA1c Date | Prior HbA1c (timeframe: 3 yr) | Medications <i>(italicized if from a different facility)</i> | |
|--------------|--------|-----|------------------------|-----------|----------------|--|-----------------------------------|--|-----------------------------------|
| | C.L.F. | 87 | N | N | 7.5 | 04/17/15 | 6.8 (07/01/14) | INSULIN NOVOLIN 70/30 (NPH/REG) INJ NOVO 25 UNITS QAM & 10 UNITS QPM | |
| | | | | | 01/31/13 | Hypoglycemia (2-3 Per Month), Faintness (None Reported), Hypoglycemic Related Visit (No) | Hypoglycemic Management-Relax | | |
| | | | | | 05/15/14 | Hypoglycemia (2-3 Per Month), Faintness (None Reported), Hypoglycemic Related Visit (No) | Hypoglycemic Management-Relax | | |
| | | | | | 04/17/15 | Hypoglycemia (Once A Week), Faintness (None Reported), Hypoglycemic Related Visit (No) | Hypoglycemic Management-Relax | | |
| | A.M.P. | 89 | N | N | 7.2 | 04/26/16 | 9.2 (06/15/15) | INSULIN GLARGINE SOLOSTAR PEN INJ (nonVA) 24 UNITS SUBCUTAN ONCE DAILY INSULIN HUMAN FLEXPEN ASPART (NovoLOG) INJ (nonVA) 5 UNITS SUBCUTANEOUSLY THREE TIMES A DAY ONLY IF NEEDED | |
| | | | | | 12/18/14 | Hypoglycemia (Once), Faintness (None Reported), Hypoglycemic Related Visit (No) | Hypoglycemic Management-No Change | | |
| | W.L.F. | 72 | N | Y (2.0) | 6.9 | 02/26/15 | | INSULIN GLARGINE HUMAN 100 UNIT/ML INJ SOLOSTAR 3ML 17 units | |
| | G.W.T. | 88 | N | Y (3.8) | 6.2 | 12/17/15 | 6.7 (06/18/14) | INSULIN DETEMIR HUMAN 100 UNIT/ML INJ FLEXTOUCH 3ML 25 UNITS | |
| | | | | | 06/18/14 | Hypoglycemia (Once A Week), Faintness (None Reported), Hypoglycemic Related Visit (No) | Hypoglycemic Management-Relax | | |
| | J.W.T. | 86 | Y | N | 7.8 | 01/21/16 | 6.3 (03/04/15) | DEXTROSE 15GM/37.5GM SQUEEZE TUBE 1 TUBE ONCE PRN INSULIN NPH HUMAN 100 U/ML INJ NOVOLIN N 25 UNITS QAM & 25 UNITS QPM | |
| | | | | | 07/28/15 | | Hypoglycemic Management-No Change | | |
| | G.W.T. | 93 | N | N | 6.8 | 11/16/15 | 7.0 (09/01/13) | GLIMEPIRIDE 2MG TAB (nonVA) 2MG BY MOUTH ONCE DAILY SITAGLIPTIN PHOSPHATE 50MG TAB (nonVA) 25MG BY MOUTH ONCE DAILY GLIPIZIDE 5MG TAB 2.5 QAM WM | |
| | | | | | 6.0 | 05/03/16 | 6.5 (03/15/16) | | |
| | H.W.T. | 69 | N | Y (2.1) | | 05/07/15 | | Hypoglycemia (None Reported) | Hypoglycemic Management-No Change |
| | | | | | 03/13/16 | | Hypoglycemic Management-No Change | | |
| | H.W.T. | 73 | N | Y (2.4) | 6.7 | 03/30/15 | | INSULIN ASPART HUMAN 100U/ML NOVOLOG FLEXPEN 3ML 20-25 UNITS TID INSULIN GLARGINE HUMAN 100 UNIT/ML INJ SOLOSTAR 3ML 40 units BID | |

Parameters

Facility

Division

Team

Primary Provider

Associate Provider

Cohort/Evaluation Status ("evaluated" means use of the Hypoglycemia Screening QRS Tool)

Not Currently in Risk Cohort, Previous

☒ (Select All)

☒ Not Currently in Risk Cohort, Previously Evaluated

☒ Currently in Risk Cohort, Never Evaluated

☒ Currently in Risk Cohort, Evaluated Within 1 Year

☒ Currently in Risk Cohort, Evaluated > 1 Year Ago

Parameters

Facility

Division

Team

Primary Provider

Associate Provider

Cohort/Evaluation Status (evaluated means use of the Hypoglycemia Screening CPRS Tool)

Not Currently in Risk Cohort, Previous

☒ (Select All)
☒ Not Currently in Risk Cohort, Previously Evaluated
☒ Currently in Risk Cohort, Never Evaluated
☒ Currently in Risk Cohort, Evaluated Within 1 Year
☒ Currently in Risk Cohort, Evaluated > 1 Year Ago

Pilot Findings

Evaluation

Over **9,300 patients** have been **evaluated** using the EMR template

Evaluation rate for high-risk patients assigned to primary care is **87%**

Occurrence

Hypoglycemia has been reported by **25%** of those evaluated

Action

Of all patients evaluated, **95%** have **documented shared decision making**

Of those reporting hypoglycemia, **56%** have made a **shared decision** with their provider to **relax treatment**

Patient Cases

- 63 yo with recent worsening of blood sugar control noted at annual PCP appt, so was referred to PharmD. Pt on Glipizide 20mg twice daily. At initial PharmD visit, patient reported that since PCP appt, he has gotten back on track with diet and now having low BG. Additionally, patient was not taking glipizide with meals as directed. Discussed nutrition issues and medication safety. Subsequent sugars are well controlled without ongoing lows.
- 79 yo with h/o significant HF and CAD identified via EMR tools/VHA HSI. Pt on 3 oral medications for diabetes and had a recent A1c of 6.3%. Discussed risks/benefits of various A1c goals with patient and determined A1c goal 7-8% was most appropriate. Was able to discontinue 1 medication, reduce another and maintain A1c at goal.

An iceberg floating in a blue ocean under a blue sky with light clouds. The tip of the iceberg is above the water, while the much larger, more complex structure is submerged below the surface. The water is a deep blue, and the sky is a lighter blue with wispy white clouds.

Hypoglycemia

Shared decision making
Individualized A1c goals
Food sufficiency
Medication safety

Key VHA CW-HSI Messages

Hypoglycemic Safety

- Provide patients with information on symptoms, management and ways to lower their risk

Shared Decision Making (SDM)

- Give both patients and providers the skills needed for SDM, including health literacy & numeracy

A1c Goals

- Disseminate information about A1c accuracy and individualizing targets

Food Sufficiency

- Educate both providers and patients about potential barriers and solutions to food insufficiency

Medication Safety

- Ensure providers and patients have an understanding of potential risks of medications

Patient & Provider Educational Resources

VA Pulse VHA HSI Website: [Requires VA email address]

- <https://www.vapulse.net/community/choosing-wisely-at-the-va/hypoglycemia-safety-initiative>
- Includes information on presentations being given both internally & externally

Hypoglycemia Safety Initiative - Quality, Safety & Value

- <https://www.qualityandsafety.va.gov/ChoosingWiselyHealthSafetyInitiative/HypoglycemiaSite/Hypoglycemia.asp>

VHA Choosing Wisely HSI ListServ

Patient & Provider Educational Resources

VA/DoD Guidelines

- <https://www.healthquality.va.gov/>

National Center for Health Promotion and Disease Prevention

- <https://www.prevention.va.gov/>

Patient Facing Videos – “Patients as Partners”

- Available on Veteran’s Health Library and YouTube
- Ideal for social media and CCTV

VA Nutrition & Food Service

- <https://www.nutrition.va.gov/>

Coming Soon

Additional tools to focus on Shared Decision Making are in the works and include:

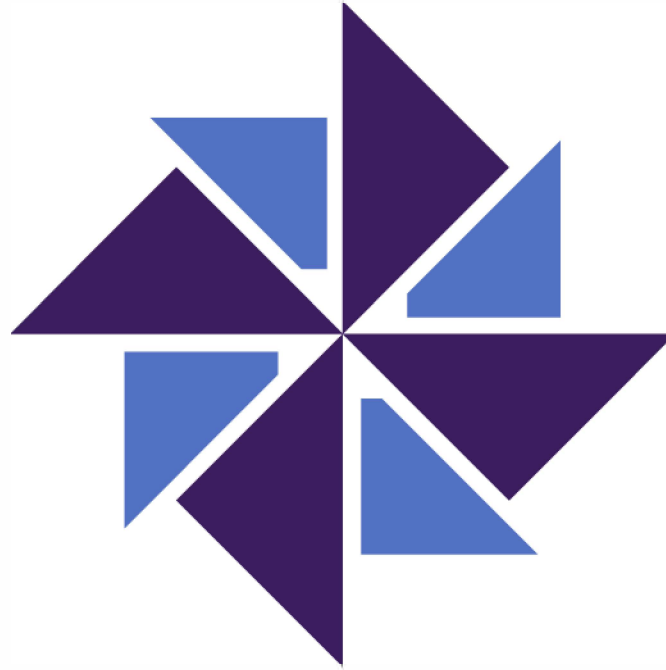
- Shared Decision Interactive Module to guide providers through SDM, highlighting the AHRQ SHARE Model
- Share Decision Interactive Module to guide patients to explore their preferences and values as it relates to their diabetes

Questions??



References

1. Management of Diabetes Mellitus. VA/DoD Clinical Practice Guideline. August 2010. Available at: http://www.healthquality.va.gov/guidelines/CD/diabetes/DM2010_FUL-v4e.pdf
2. U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion. (2014). National Action Plan for Adverse Drug Event Prevention. Washington, DC: Author.
3. Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models; Proposed Rule, 81 Fed. Reg. 89 (May 9, 2016). *Federal Register: The Daily Journal of the United States*. Web. 14 October 2016.
4. Feil DG et al. Risk of of hypoglycemia in older veterans with dementia and cognitive impairment: implications for practice and policy. *J Am Geriatr Soc*. 2011 Dec;59(12):2263-72.
5. Caverly TJ et al. Appropriate Prescribing for Patients With Diabetes at High Risk for Hypoglycemia: National Survey of Veterans Affairs Health Care Professionals. [JAMA Intern Med](#). 2015 Dec;175(12):1994-6.



INSTITUTE FOR PATIENT- AND FAMILY-CENTERED CARE

www.ipfcc.org

Patient- and Family-Centered Care: The Experience of Living with Type One Diabetes

Beverley H. Johnson
IPFCC President and CEO

“Partnering to Prevent Hypoglycemia”
Listening Session

November 1, 2017 — Washington, DC



Patient- and Family-Centered Care Core Concepts

- ◆ People are treated with **respect and dignity**.
- ◆ Health care providers communicate and share complete and unbiased **information** with patients and families in ways that are affirming and useful.
- ◆ Patients and families are encouraged and supported in **participating in care and decision-making** at the level they choose.
- ◆ **Collaboration** among patients, families, and providers occurs in policy and program development, QI and safety, professional education, and research as well as in the delivery of care.





Patient- and family-centered care is working "with" patients and families, rather than just doing "to" or "for" them.



Challenges at the Intersection of Team-Based and Patient-Centered Health Care

Insights From an IOM Working Group

Matthew K. Wynia, MD, MPH

Isabelle Von Kohorn, MD, PhD

Pamela H. Mitchell, PhD, RN

are used to describe team-based care, the patient is the quarterback. Is the patient the quarterback? The team has a different quarterback or coach. How would this vary according to the team's purpose? For example, teams for patients receiving

“In high-functioning health care teams, patients are members of the team; not simply objects of the team’s attention...”



THE VISION

A health system that performs optimally in promoting, protecting, and restoring the health of individuals and populations, and helps each person reach their full potential for health and well-being.

CORE GOALS

Better Health
& Well-being

High-Value
Health Care

Strong Science
& Technology

ACTION PRIORITIES

- Pay for value
- Empower people
- Activate communities
- Connect care

ESSENTIAL INFRASTRUCTURE NEEDS

- Measure what matters most
- Modernize skills
- Accelerate real-world evidence
- Advance science

“Vital Directions for Health and Health Care” National Academy of Medicine

- ◆ “...reforms need to ensure that patients and families are fully informed and able to participate as partners in determining outcomes and values for their own health and health care.”
- ◆ “Empowering individuals to make informed, personal health decisions requires giving them ownership of their own health data”

“Vital Directions for Health and Health Care: Priorities from a National Academy of Medicine Initiative,” National Academy of Medicine, 2017.



The diagnosis of Type One Diabetes and
the challenges of finding a care team.



Sharing Stories as a Strategy to Change Organizational Culture and Guide Policy and Program Development

*“Facts bring us to knowledge,
Stories bring us to wisdom.”*

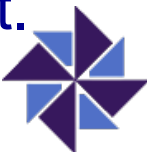
Rachel Remen



Patient- and Family-Centered Care or the Lack Thereof

- ◆ I asked to see my A1C levels before I met with the doctor. The nurse said, “**The doctor does not do it that way. He will give you the results.**” After a brief discussion, she said that she would give my lab report to me this time, but “**do not ever ask again!**”
- ◆ The following week, I met with the physician. The very first thing he said to me was, “**I do not want you wasting my staff’s time.**”

Lack of respect, lack of information sharing, lack of support and encouragement for the patient to be actively engaged in care, and lack of collaboration in managing a chronic condition that requires the patient almost hourly involvement.



Challenge of Obtaining Supplies



Serious “Low” While Traveling



- ◆ New pump user . . . Used insulin to cover snacks during a breakfast-time flight.
- ◆ Tampa Airport Shuttle to Clearwater Meeting.
- ◆ Talking on cell phone when three other passengers boarded the shuttle.
- ◆ Awakened to a fire truck and an EMT checking my blood sugar.



Continuous Glucose Monitor (CGM)

- ◆ To keep me safe and prevent hypoglycemia and “lows,” a continuous glucose monitor would be very helpful and prevent ED visits and hospitalizations.
- ◆ Until very recently, I have been told that Medicare would not cover a continuous glucose monitor.



Notice of Noncoverage: Medicare Rules Prohibit Use of Mobile Devices

“I understand that Medicare coverage rules for therapeutic CGM supplies require that I only use the Dexcom receiver to display my CGM glucose data. Thus, I understand that my CGM supplies are not covered by Medicare if I use a smart phone, tablet, or other mobile device to view my glucose data, even if I also use my Dexcom receiver. **Finally, I understand that if I access my CGM readings on a mobile device, I will lose Medicare coverage retroactively for the entire period during which I violated this Medicare coverage rule** and may be required to pay Dexcom's full charges for CGM supplies I received that should not have been covered and/or to reimburse Dexcom for refunds and/or penalties Dexcom is required to pay with respect to my CGM supplies.”



-
- ◆ My daughter, who is a physician, also has Type One Diabetes...she was diagnosed the day before she took her Medical Boards at the age of 29. She is peer support for me
 - ◆ Her first weekend living with diabetes, a major discovery was how little she knew about what it was like to live with diabetes. She realized that her residency had taught her the clinical aspects of diabetes, but had not prepared her for providing practical advice to support patients and families living with this chronic condition.
 - ◆ Another discovery was that almost every two hours, she was aware that she was living with diabetes. Decades later, I understood this discovery and the “new normal.” It is a constant.



Information Model vs. Medical Model For Reducing Hypoglycemia and a “Low”

- ◆ Pre-visit Information and Planning
- ◆ Waiting Room
 - ◆ Bulletin Board and Tabletop Information
 - ◆ Computer and TV
- ◆ Exam Room
 - ◆ Computer and/or a Big Screen
 - ◆ Information & Tools Displayed and Accessible for Take Home
 - ◆ Action Plan
- ◆ After Visit
 - ◆ After Visit Summary and Clinical Notes (OpenNotes)
- ◆ Between Visit Reminders, Information Sharing, Peer Support

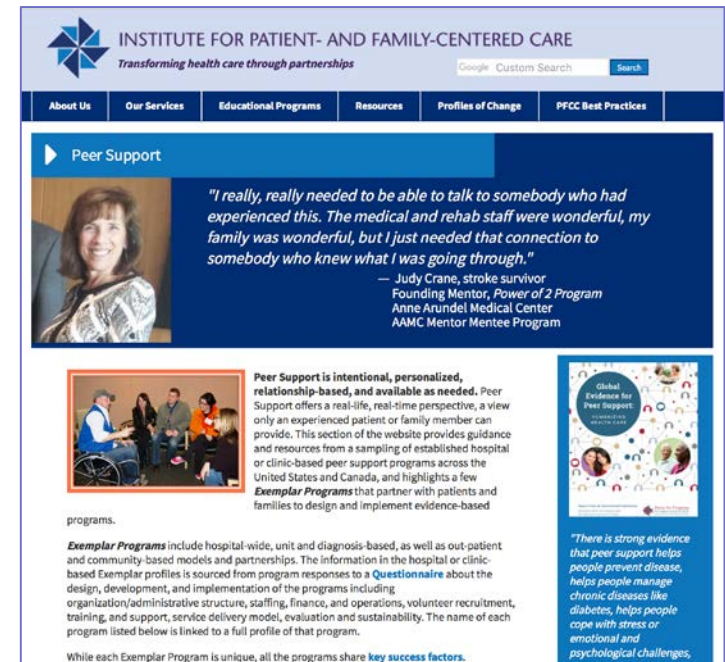


Missed Opportunity for Peer Support

"I have had Type One Diabetes for 28 years, and I have NEVER met another person with Type One.

I have just been declared legally blind."

A Hospital Staff Member at a Training on Patient- and Family-Centered Care and Reducing Unnecessary Hospital Readmissions



The screenshot shows the IPFCC website header with the logo and tagline "Transforming health care through partnerships". The navigation bar includes links for About Us, Our Services, Educational Programs, Resources, Profiles of Change, and PFCC Best Practices. The main content area is titled "Peer Support" and features a quote from Judy Crane, a stroke survivor and Founding Mentor of the Power of 2 Program at Anne Arundel Medical Center. Below the quote is a photo of Judy Crane. To the right, there is a section titled "Peer Support is intentional, personalized, relationship-based, and available as needed." which describes the program's goals and provides a link to a questionnaire. At the bottom, there is a section titled "Exemplar Programs" which lists various programs and their key success factors.

INSTITUTE FOR PATIENT- AND FAMILY-CENTERED CARE
Transforming health care through partnerships

Google Custom Search Search

About Us Our Services Educational Programs Resources Profiles of Change PFCC Best Practices

▶ Peer Support

"I really, really needed to be able to talk to somebody who had experienced this. The medical and rehab staff were wonderful, my family was wonderful, but I just needed that connection to somebody who knew what I was going through."

— Judy Crane, stroke survivor
Founding Mentor, Power of 2 Program
Anne Arundel Medical Center
AAMC Mentor Mentee Program

Peer Support is intentional, personalized, relationship-based, and available as needed. Peer Support offers a real-life, real-time perspective, a view only an experienced patient or family member can provide. This section of the website provides guidance and resources from a sampling of established hospital or clinic-based peer support programs across the United States and Canada, and highlights a few **Exemplar Programs** that partner with patients and families to design and implement evidence-based programs.

Exemplar Programs include hospital-wide, unit and diagnosis-based, as well as out-patient and community-based models and partnerships. The information in the hospital or clinic-based Exemplar profiles is sourced from program responses to a **Questionnaire** about the design, development, and implementation of the programs including organization/administrative structure, staffing, finance, and operations, volunteer recruitment, training, and support, service delivery model, evaluation and sustainability. The name of each program listed below is linked to a full profile of that program.

While each Exemplar Program is unique, all the programs share **key success factors**.

Global Evidence for Peer Support

"There is strong evidence that peer support helps people prevent disease, helps people manage chronic diseases like diabetes, helps people cope with stress or emotional and psychological challenges."

www.ipfcc.org/bestpractices/peer-support.html





Questions and Comments

For further information:

Bev Johnson bjohnson@ipfcc.org



The “New Knowable” – Answering the Questions We’ve Always Wanted To (And Finally Can)

Kelly L. Close

Founder & Chair, The diaTribe Foundation

@diaTribeNews / @KellyClose

kelly.close@diaTribe.org

A1c Does Not Drive Hypoglycemia

- Average age 76
- All on insulin

“The duration of hypoglycemia was not different between the A1c groups, regardless of treatment intensity”

- **ACCORD:** A1c ↑ ; Hypo rates ↑

J Diabetes Complications. 2017 Jul; 31(7):1197-1199.

BMJ. 2010; 340: b5444.

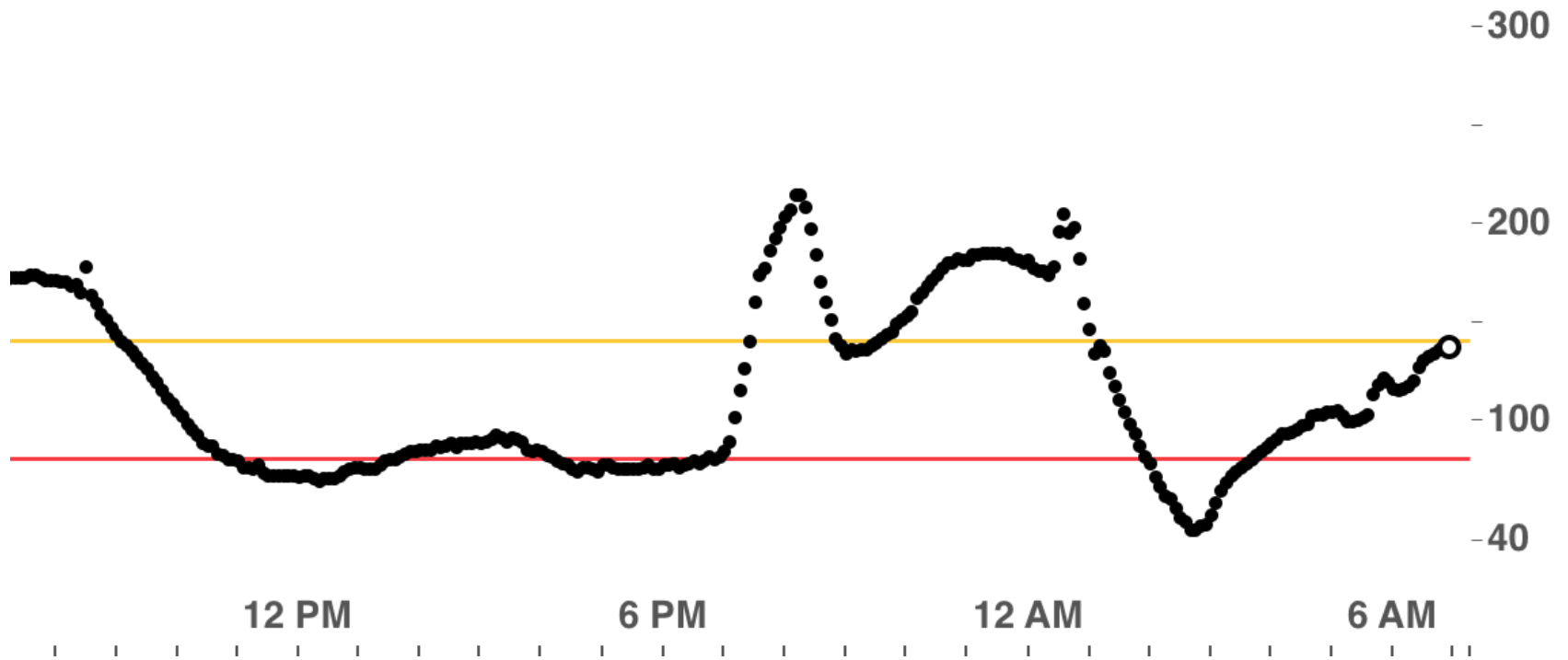
1HR

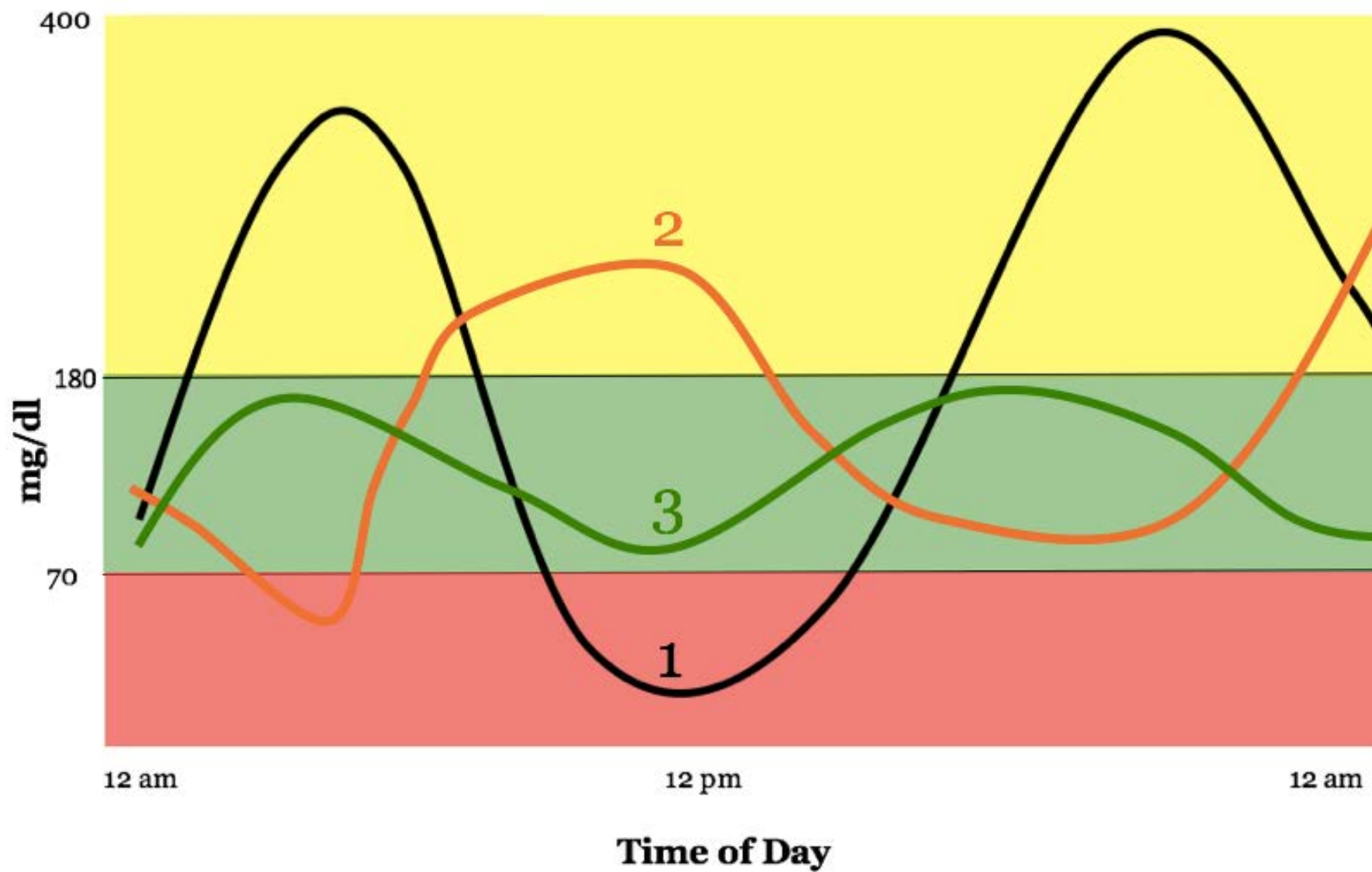
3HR

6HR

12HR

24HR





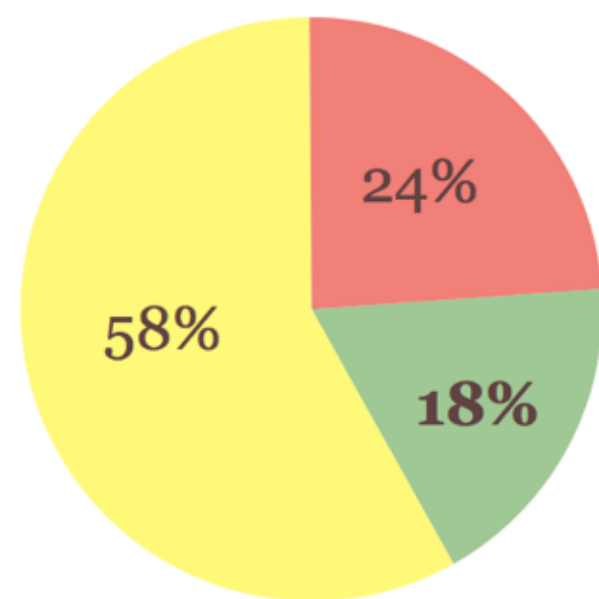
The Many Faces of a 7% A1c

Time spent

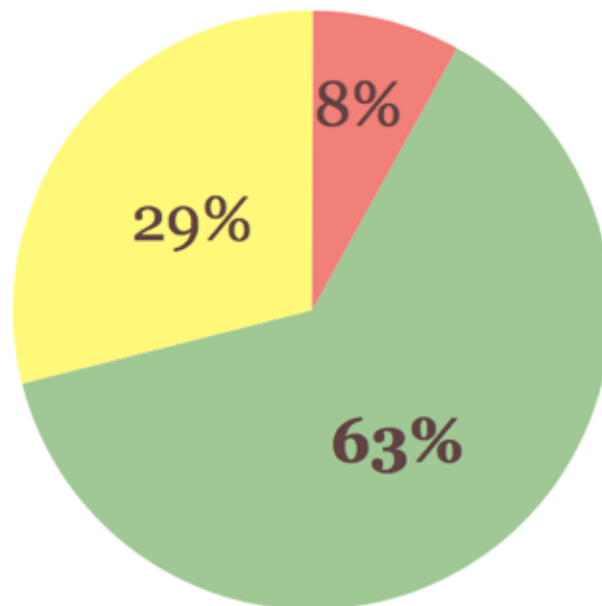
HIGH

IN RANGE

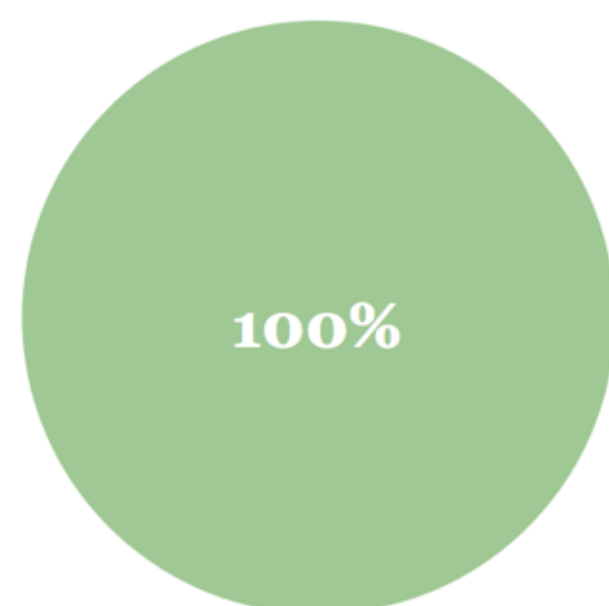
LOW



1



2



3

A1c tells us nothing about hypoglycemia, which:

- Can be fatal and life threatening TODAY;
- Is responsible for an estimated ~5-10% of deaths in type 1 diabetes;
- Is typically cited as the biggest barrier to tighter glycemic control; and
- Drives an estimated **~\$10+ billion in US healthcare claims, ~\$3 billion in lost productivity,** and ~300,000 US hospitalizations and ER visits annually.

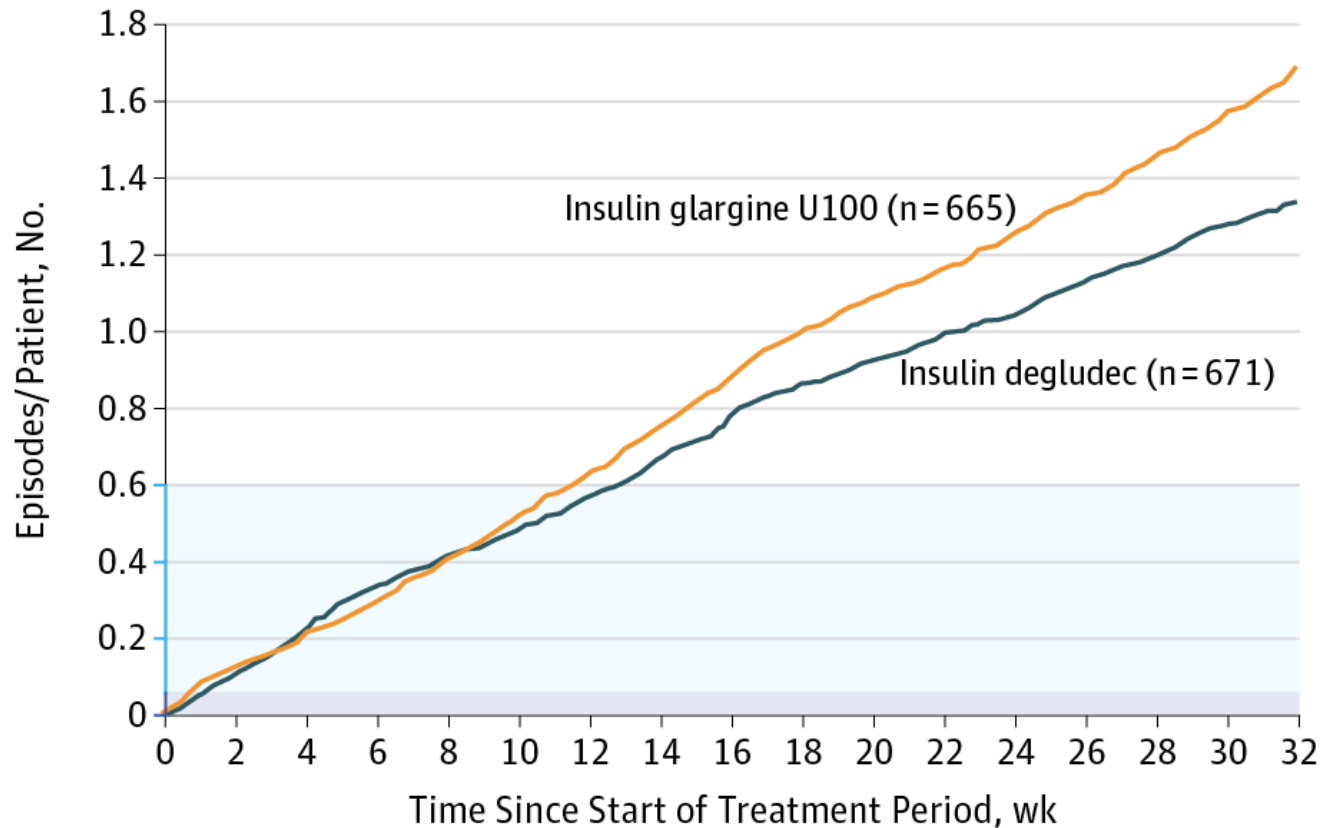
The New Knowable

Which drugs have the most and least hypoglycemia?

The SWITCH 2 Trial

Full treatment period

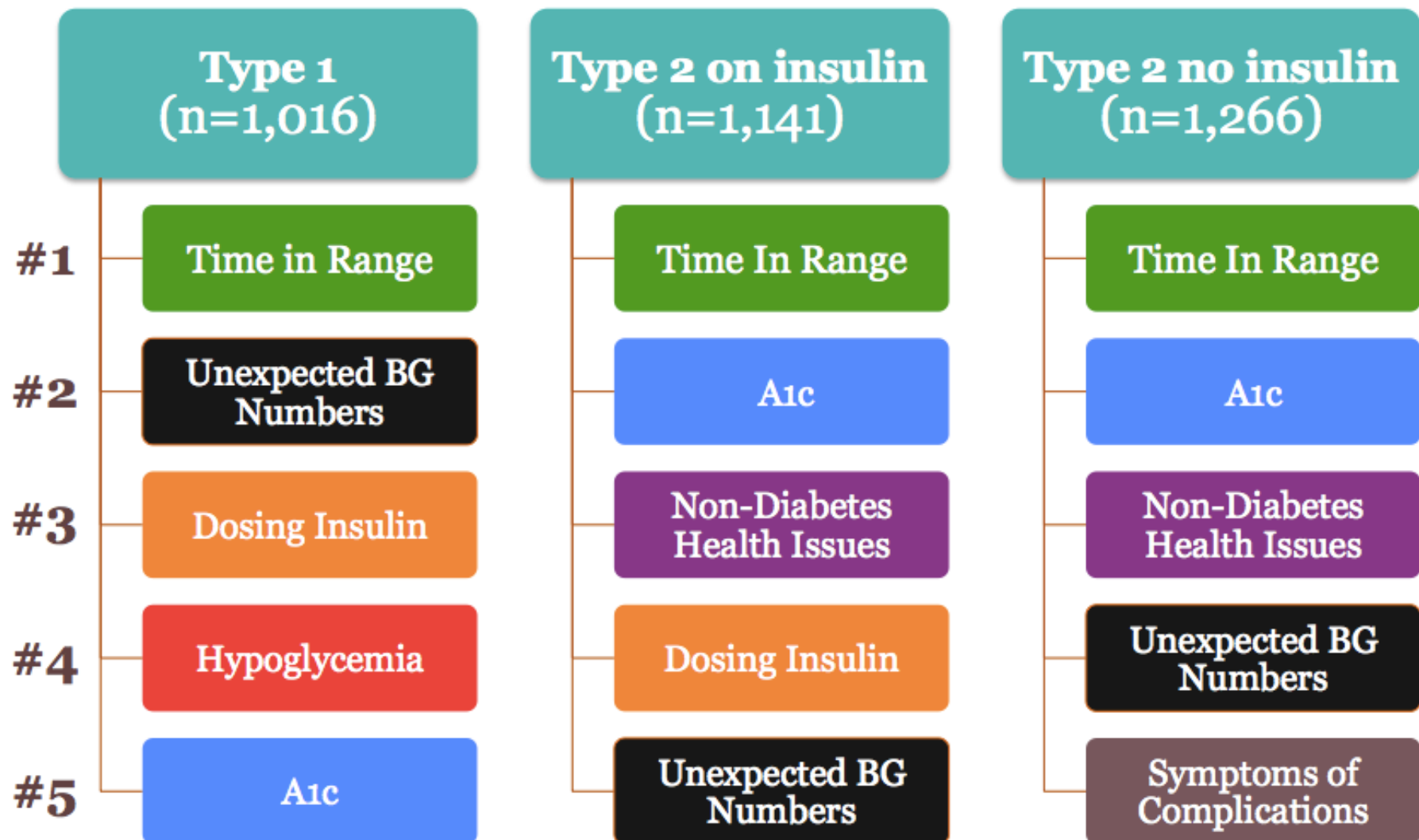
B Overall symptomatic hypoglycemia



The New Knowable

Is it possible that time-in-range
or hypoglycemia might influence
adherence?

“A Big Impact” on Daily Life, Rank Order: Many differences, but time-in-range is #1 for all



“A Big Impact” on Daily Life, Rank Order: Many differences, but time-in-range is #1 for all

Type 1
(n=1,016)

Type 2 on insulin
(n=1,141)

Type 2 no insulin
(n=1,266)

#1

Time in Range

Time In Range

Time In Range

#2

Unexpected BG
Numbers

A1c

A1c

#3

Dosing Insulin

Non-Diabetes
Health Issues

Non-Diabetes
Health Issues

#4

Hypoglycemia

Dosing Insulin

Unexpected BG
Numbers

#5

A1c

Unexpected BG
Numbers

Symptoms of
Complications

The New Knowable

How much time do people on insulin spend in hypoglycemia during the workday?

What impact does this have on their productivity?

Hospitalizations for Hypoglycemia/DKA

(Days/100 patient years)

Before CGM

54

After CGM

18

Work Absenteeism

(Days/100 patient years)

Before CGM

495

After CGM

234

The New Knowable

What is the correlation between time or frequency of hypoglycemia and long-term complications or mortality?

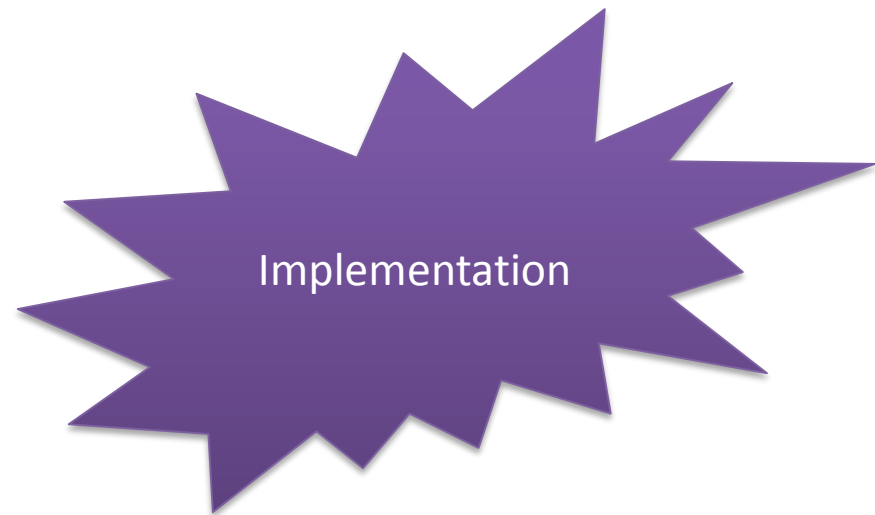


THE **diaTribe**
FOUNDATION

The Action in the Action Plan

Christine Lee, PharmD, PhD

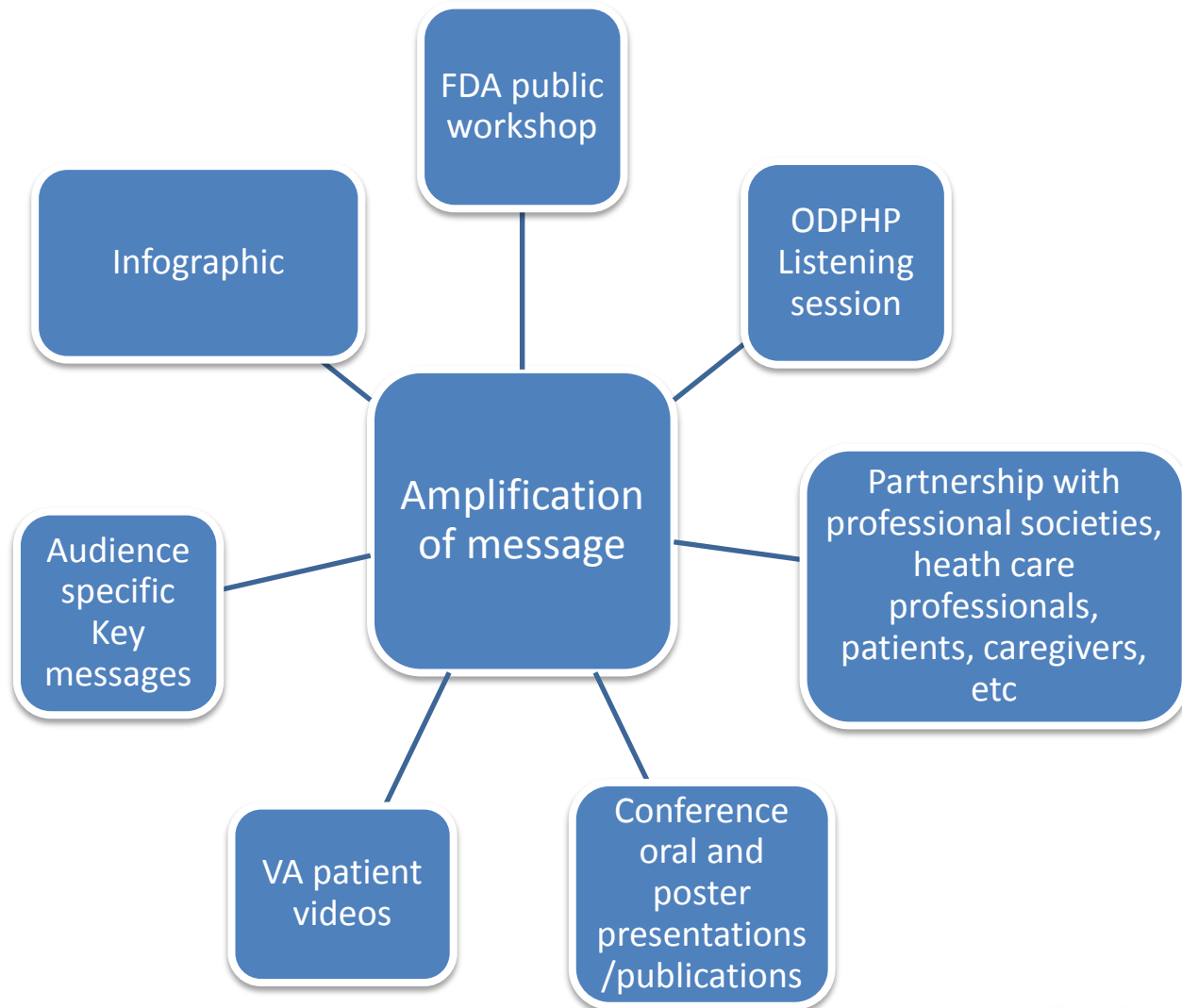
FDA Safe Use Initiative, PASE



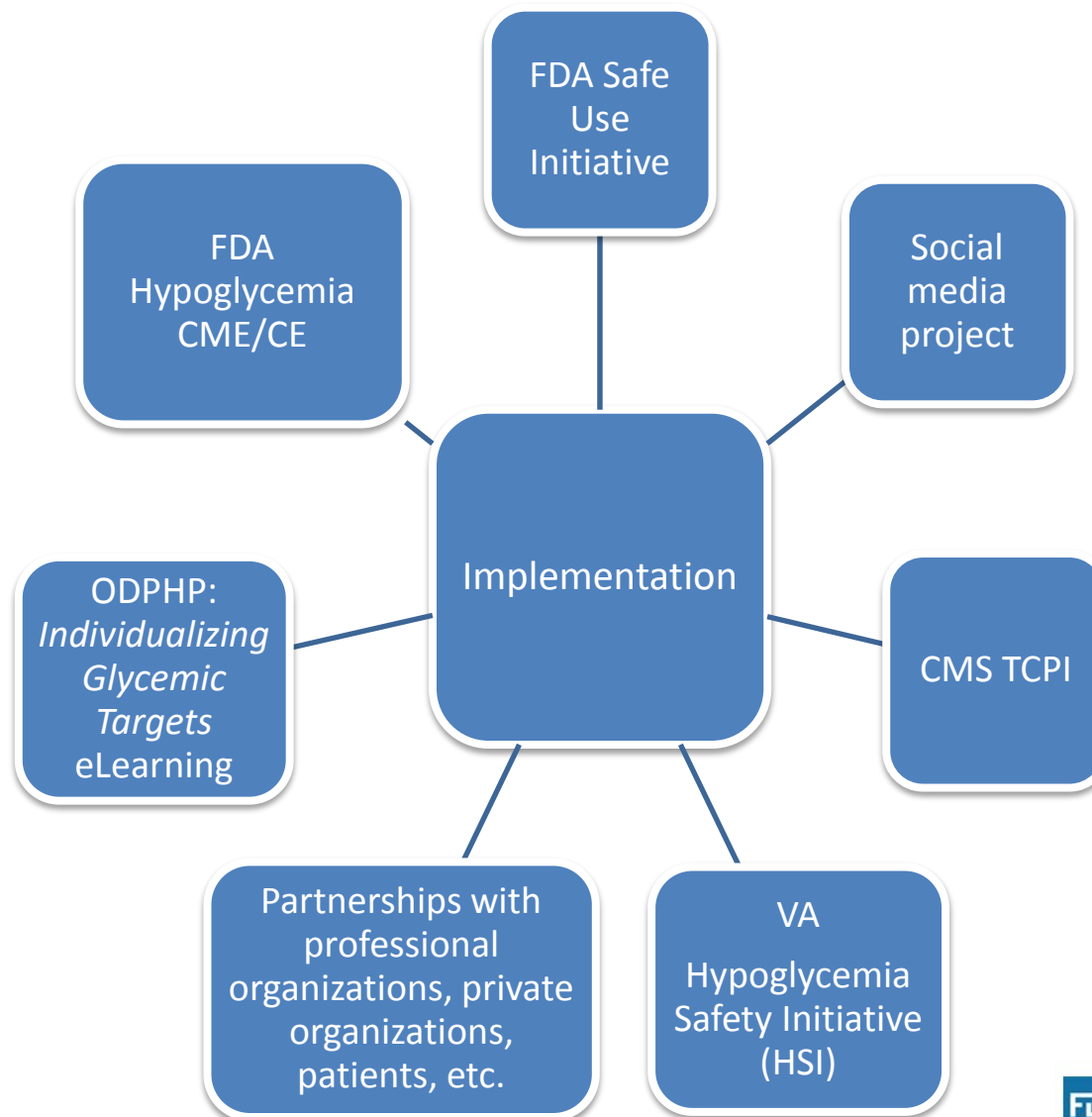
Leveraging FDA Safe Use partnerships in ACTION

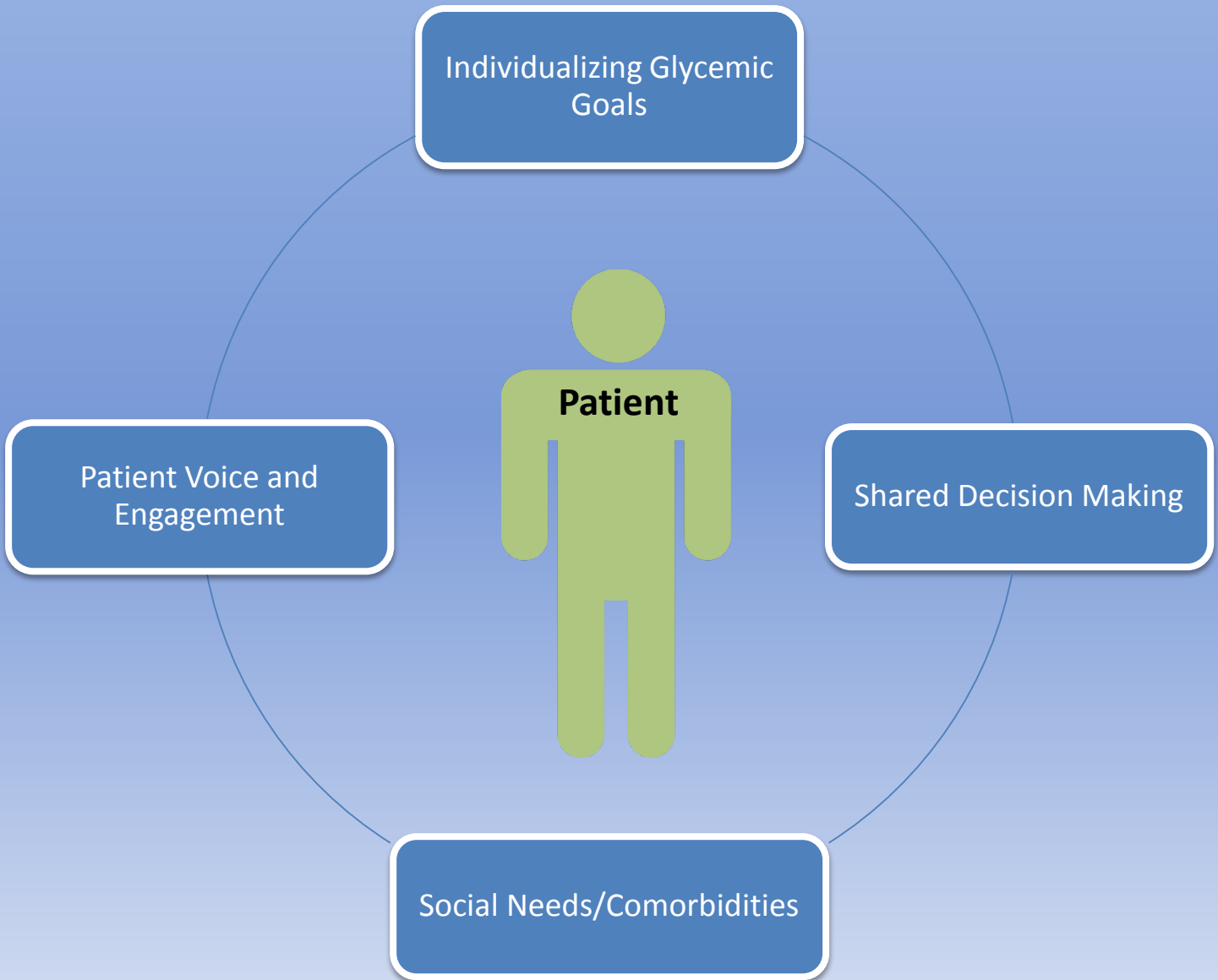


Dissemination efforts



Implementation efforts





**The Veterans Administration/Department of Defense
2017 Guidelines for Management of Type 2 Diabetes
Evidence Patients, Family Members and
Clinicians Need to Know to Make *Informed
Decisions Using* Shared Decision Making**

Partnering to Prevent Hypoglycemia

Department Health and Human Services November 1 2017

Presented by Leonard Pogach MD, MBA, FACP

National Director Medicine/Specialty Care Services

Office of Policy and Services /Veterans Health Administration

On behalf of the VA/DoD Diabetes Clinical

Practice Guideline Workgroup

Disclaimer

- The views expressed in this presentation are not to be construed as those of the U.S. Department of Veterans Affairs or the U.S. Department of Defense.
- The VA/DoD Clinical Practice Workgroup Members disclosed no conflicts of interest.

Health and Human Services National Action Plan to Prevent ADEs-Diabetes Agents 2014

- “The American Diabetes Association (ADA) Standards of Medical Care in Diabetes and the ADA/American Geriatric Society (AGS) guidelines, as well as the Department of Veterans Affairs and Department of Defense (VA/DOD) guidelines, all interpret the scientific evidence as supporting individualization target glycemic goals based on life expectancy, co-morbid conditions, social support, and personal preference.”

Demographics of Veterans With Diabetes

FY 2017

1 in 4 Veterans (~1.5 million) receiving care in the
VA has **diabetes**

~70% of Veterans with diabetes are 65 and older

~30% of older Veterans receive insulin

~60% have significant co-morbid conditions

Provided by: **VHA Support Service Center** (VSSC in the office of Organizational Excellence. April 2017)

VA/DoD Guidelines 2003

- The target **value for an individual patient** considers the approximate risk-to-benefit ratio of the treatment necessary to achieve it
- Health care providers and their patients to establish **individually negotiated targets** based on **personal preferences** and **individually appraised risks and benefits**.
- **Intensive glycemic control** is known to **increase** the incidence and severity of **hypoglycemia**.

2017: Develop Individualized Treatment Plans Based on Complications, Comorbidities, Life Expectancy, and Patient Preferences. www.healthquality.va.gov/guidelines/CD/diabetes/

- The CPG proposes HbA_{1c} target ranges (rather than an all-or-nothing target value) based on the presence or absence of microvascular complications, comorbidities, social determinants of health, life expectancy and social determinants of health.
- The overarching goal is to use Shared Decision Making to develop individualized treatment plans to achieve HbA_{1c} target ranges that are tailored to a patient's unique characteristics and goals of care, taking into account patient preference and potential benefits and harms.

Annals of Internal Medicine CLINICAL GUIDELINE

Synopsis of the 2017 U.S. Department of Veterans Affairs/ U.S. Department of Defense Clinical Practice Guideline: Management of Type 2 Diabetes Mellitus

- **Description:** In April 2017, the U.S. Department of Veterans Affairs (VA) and the U.S. Department of Defense (DoD) approved a joint clinical practice guideline for the management of type 2 diabetes mellitus.
- **Methods:** The VA/DoD Evidence-Based Practice Work Group convened a joint VA/DoD guideline development effort that included a multidisciplinary panel of practicing clinician stakeholders and conformed to the Institute of Medicine's tenets for trustworthy clinical practice guidelines. The guideline panel developed key questions in collaboration with the ECRI Institute, which systematically searched and evaluated the literature through June 2016, developed an algorithm, and rated recommendations by using the GRADE (Grading of Recommendations Assessment, Development and Evaluation) system.
- **Recommendations:** This synopsis summarizes key features of the guideline in 7 areas: **patient-centered care and shared decision making, glycemic biomarkers, hemoglobin A1c target ranges, individualized treatment plans**, outpatient pharmacologic treatment, glucose targets for critically ill patients, and treatment of hospitalized patients.
- *Ann Intern Med.* 2017;167:Vol. 167 No. 9 • 7 November 2017
- This article was published at Annals.org on 24 October 2017.

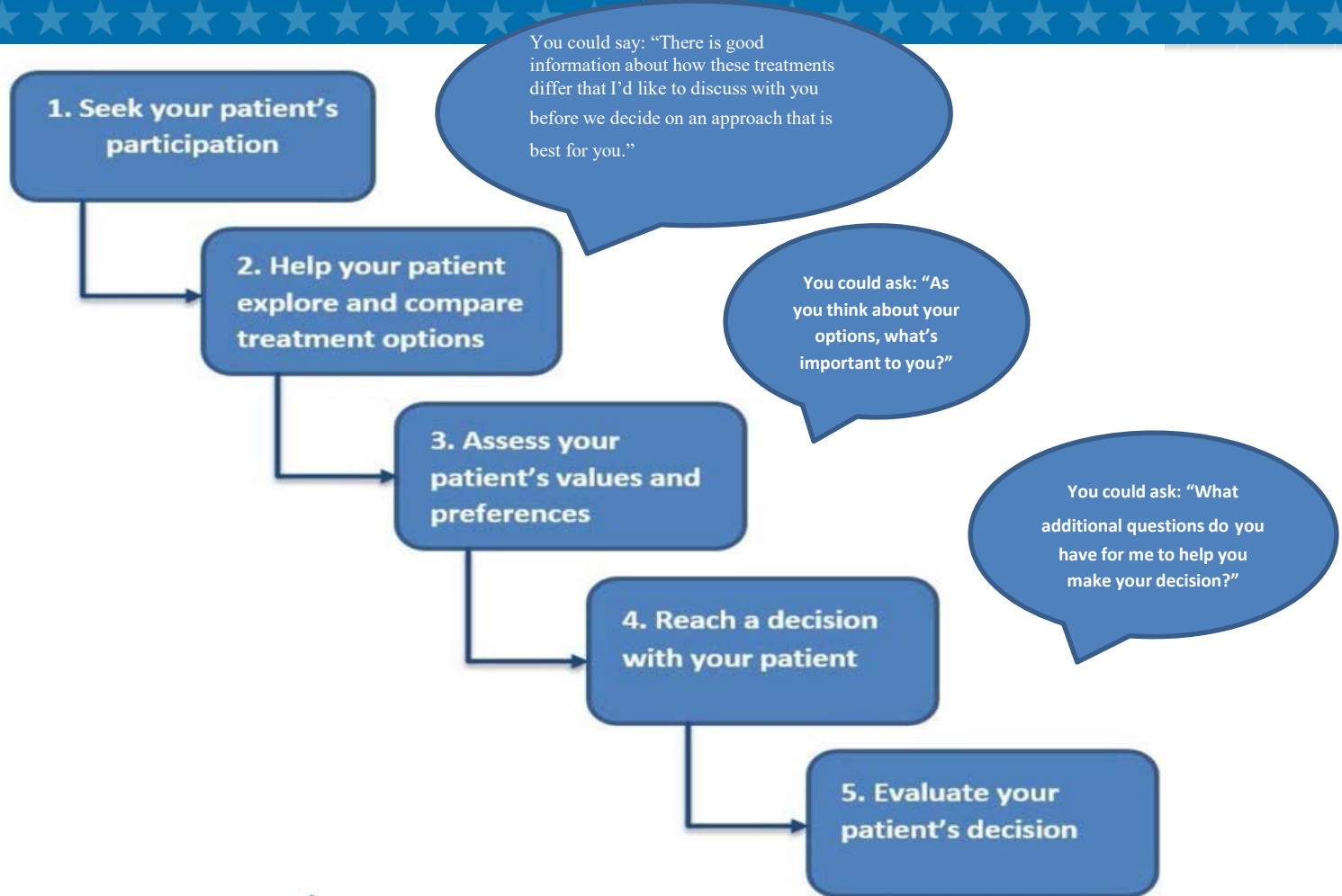
Key Recommendations of 2017 VA/DoD Diabetes Guidelines- Shared Decision Making

www.healthquality.va.gov

| # | Recommendation | Strength | Category |
|----------------------------------|---|------------|------------------------|
| B. Shared Decision Making | | | |
| 4. | SDM should be included, at a minimum, at the time of diagnosis, during difficulties with management, and at times of transition or development of complications | Strong for | Reviewed, New-added |

- Greater knowledge of medications and understanding of risks.
- Decrease patient anxiety, increase trust in clinicians, and improve treatment adherence

How to Apply the SHARE Model

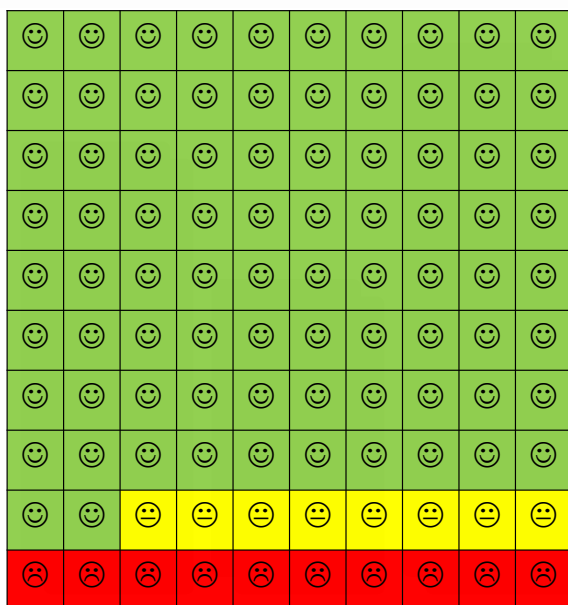


Key Recommendations of 2017 VA/DoD Diabetes Guidelines- MAGNITUDE OF BENEFIT

| # | Recommendation | Strength | Category |
|---|--|------------|------------------------|
| B. Glycemic Control Targets and Monitoring | | | |
| 4. | We recommend setting an HbA1c target range based on absolute risk reduction (ARR) of significant microvascular complications, life expectancy, patient preferences and social determinants of health. | Strong for | Reviewed, New-added |

- In **UKPDS 33**, there was a 37% RRR for microvascular complications that was continuous and without a threshold. The ARR for any microvascular complication was 5.0/100 and the number needed to treat over 10 years was 19.6 upon a mean achieved A1c of 8.0% in the control group and 7.0% in the treatment group.
- GRADE does not recommend using systematic reviews to calculate the number needed to treat (NNT) and number needed to harm (NNH) because of high risk for bias: over- or under-estimation of risk.





For new onset diabetes, if A1c levels are targeted to be around 7% for the first 10 years

82 alive with diabetes without microvascular disease

8 alive with diabetes and microvascular disease

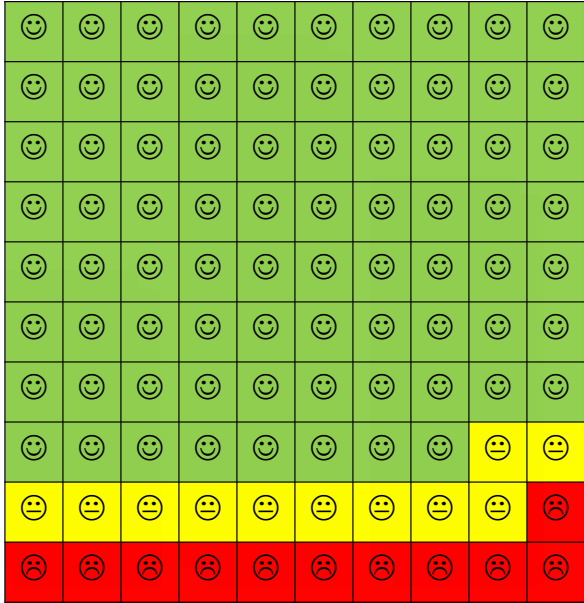
10 dead from diabetes

For new onset diabetes, if A1c levels are targeted to be around 8% for the first 10 years

78 alive with diabetes without microvascular disease

11 alive with diabetes and micro-vascular disease

11 dead from diabetes



The United Kingdom Prospective Study (UKPDS), conducted from the mid-1980s to late 1990s with patients whose average A1c was 9% at time of diagnosis, **provides the primary evidence base for tight control of type 2 diabetes from onset of disease for individuals with a life expectancy of around 10 years** - UKPDS 33 (sulfonylurea/insulin therapy compared to conventional therapy – Lancet 1998); Use of metformin may confer additional benefit; UKPDS 34 (metformin vs. conventional therapy Lancet 1988).

| | |
|--|--|
| | Person alive with diabetes and no microvascular complications |
| | Person alive with diabetes and with microvascular complications |
| | Person dead from diabetes |
| | Microvascular complications include retinopathy, nephropathy, and neuropathy |

Definitions:

Microvascular Comorbidities

Mild

- Early retinopathy, and/or microalbuminuria, and/or mild neuropathy

Moderate

- pre-proliferative retinopathy or persistent, fixed proteinuria (macroalbuminuria), and/or demonstrable peripheral neuropathy (sensory loss)

Advanced

- severe non-proliferative or proliferative retinopathy and/or renal insufficiency (Stage 3b CKD), and/or insensate extremities or autonomic neuropathy (e.g., gastroparesis, impaired sweating, orthostatic hypotension)

Key Recommendation- A1C Interpretation

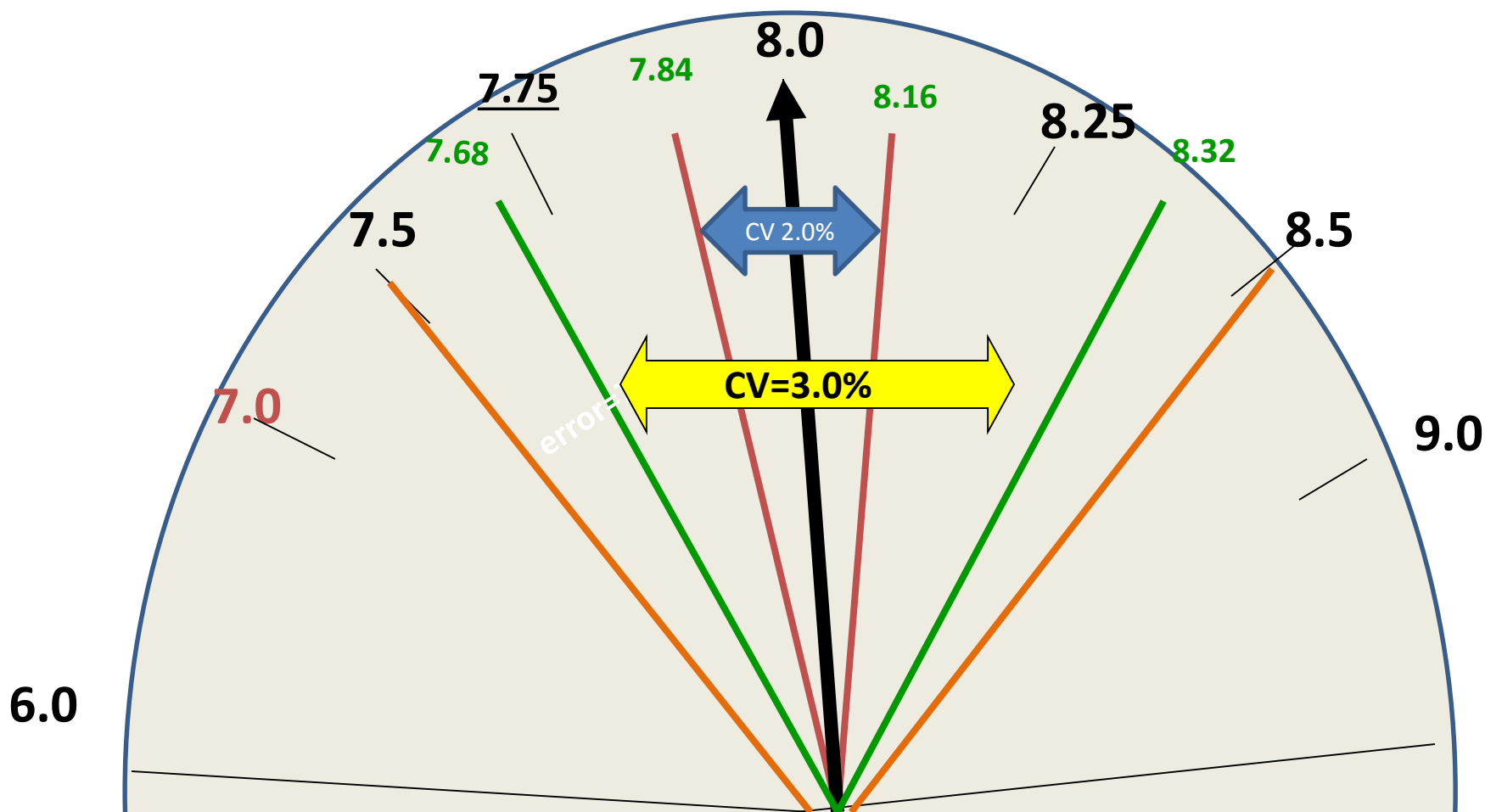
| # | Recommendation | Strength | Category |
|---|---|------------|------------------------|
| B. Glycemic Control Targets and Monitoring | | | |
| 6. | We recommend assessing patient characteristics such as race, ethnicity, chronic kidney disease, and non-glycemic factors (e.g., laboratory methodology and assay variability) when interpreting HbA1c, fructosamine and other glycemic biomarker results. | Strong for | Reviewed, New-added |

- A single HbA1c measurement, even from a high quality laboratory, has a margin of error. Its true value is within a range defined by the coefficient of variation.
- Many factors affect HbA1c measurement besides the level of glycemia such as anemia, CKD, hemoglobin variants
- African Americans have 0.4% higher A1c than Whites without differences in glycemic measures at time of entry in DPP study and ADOPT Study
- VA/DoD recommends against use of estimated average glucose which is derived from A1c values using a formula.



An A1c Test Result is Within a Range Dependent Upon the Assay

A result of 8.0% is within a 7.84 to 8.16 range from a high quality laboratory (intra-assay coefficient of variation [CV]=2.0%) and between 7.68% and 8.32% if the CV is 3.0%). A CV of 2% will produce a 95% probability that a difference of about 0.5% HbA1c between successive patient samples is a true difference 95 out of 100 times for a A1c value of 8.0%.



Encourage Numeracy, Not Measures

VHA Laboratory Result Comment

- In support of the VHA Choosing Wisely-Hypoglycemic Safety Initiative, the Pathology and Laboratory Medicine Services was asked to append the following comments to A1c reports (including both lab and POC tests):
 - **Citing performance measures or target values is not consistent with the individualized target approach advocated by the VA/DOD Guidelines**

| | | | | |
|---|-------------|-------|------------|-----------|
| Specimen: BLOOD. | SC 1124 484 | | | |
| Specimen Collection Date: Nov 24, 2015@12:55 | | | | |
| Test name | Result | units | Ref. range | Site Code |
| GLYCATED HEMOGLOBIN | 9.8 H | % | 4.0 - 6.0 | [578] |
| Comment: Target A1C values should be individualized. Better understanding of A1C test result accuracy is essential if clinicians are to interpret results for Veterans, and discuss treatment options through the process of Shared Decision Making. Contact your laboratory for performance characteristics of this assay. | | | | |

Glycemic Targets – VA/DoD 2017

- “We recommend setting an HbA1c target **RANGE** based on absolute risk reduction of significant microvascular complications, life expectancy, patient preferences and social determinants of health.” – Strong for

| Major Comorbidities or Physiologic Age | Microvascular Complications | | |
|--|-----------------------------|----------|----------|
| | Absent or Mild | Moderate | Advanced |
| Absent >10-15 years life expectancy | 6.0-7.0% | 7.0-8.0% | 7.5-8.5% |
| Present 5-10 years of life expectancy | 7.0-8.0% | 7.5-8.5% | 7.5-8.5% |
| Marked <5 years of life expectancy | 8.0-9.0% | 8.0-9.0% | 8.0-9.0% |

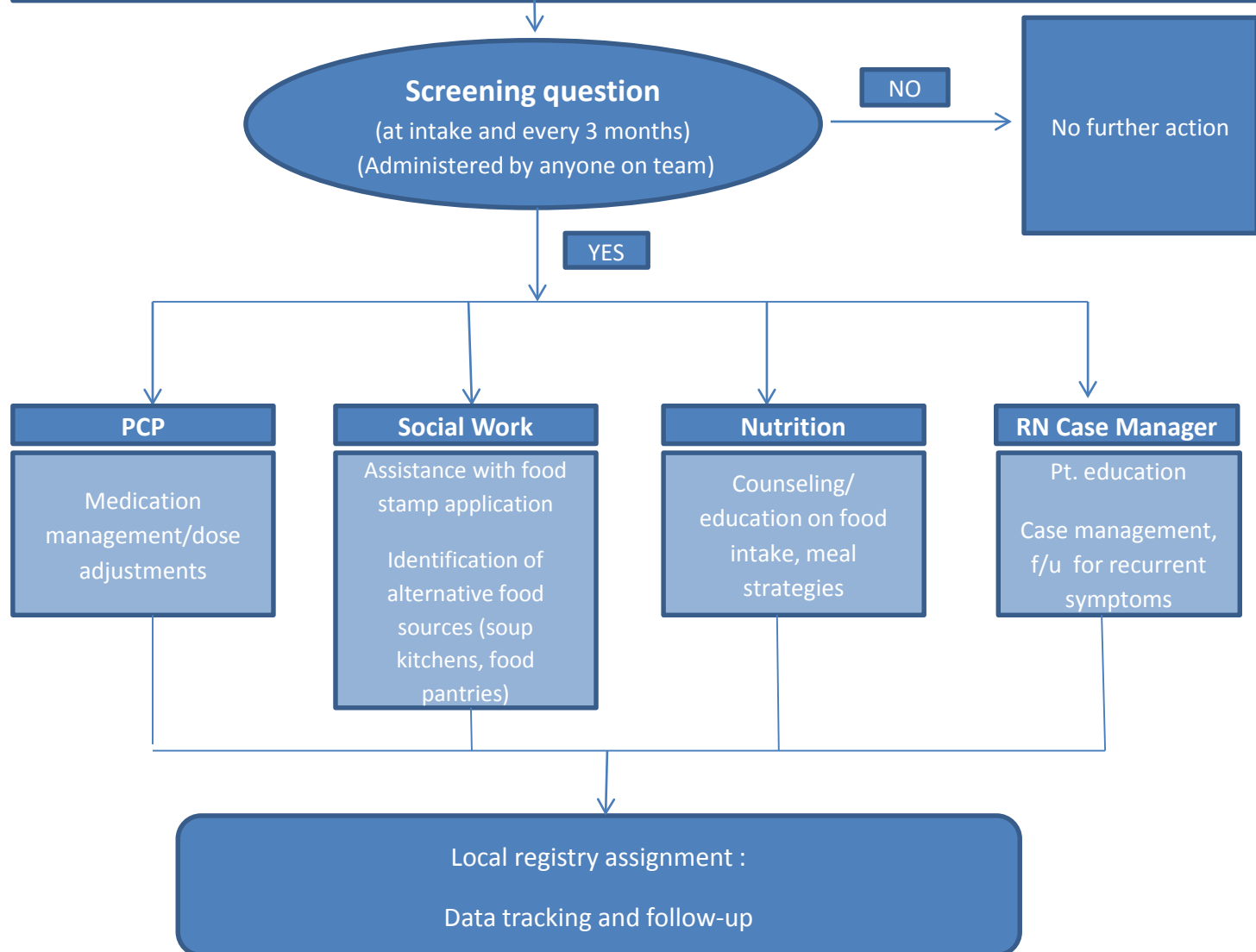
Goal 7.5-8.5%

- “...**7.5-8.5%** is appropriate for most individuals with established microvascular or macrovascular disease, comorbid conditions, or 5-10 years life expectancy, if it can be safely achieved” – Strong for
 - No evidence that A1c <8.5% lowers mortality
 - A1c <7% shows no benefit with CVD and may increase mortality
 - Individual benefits of glycemic control must be balanced against risks of medication therapy

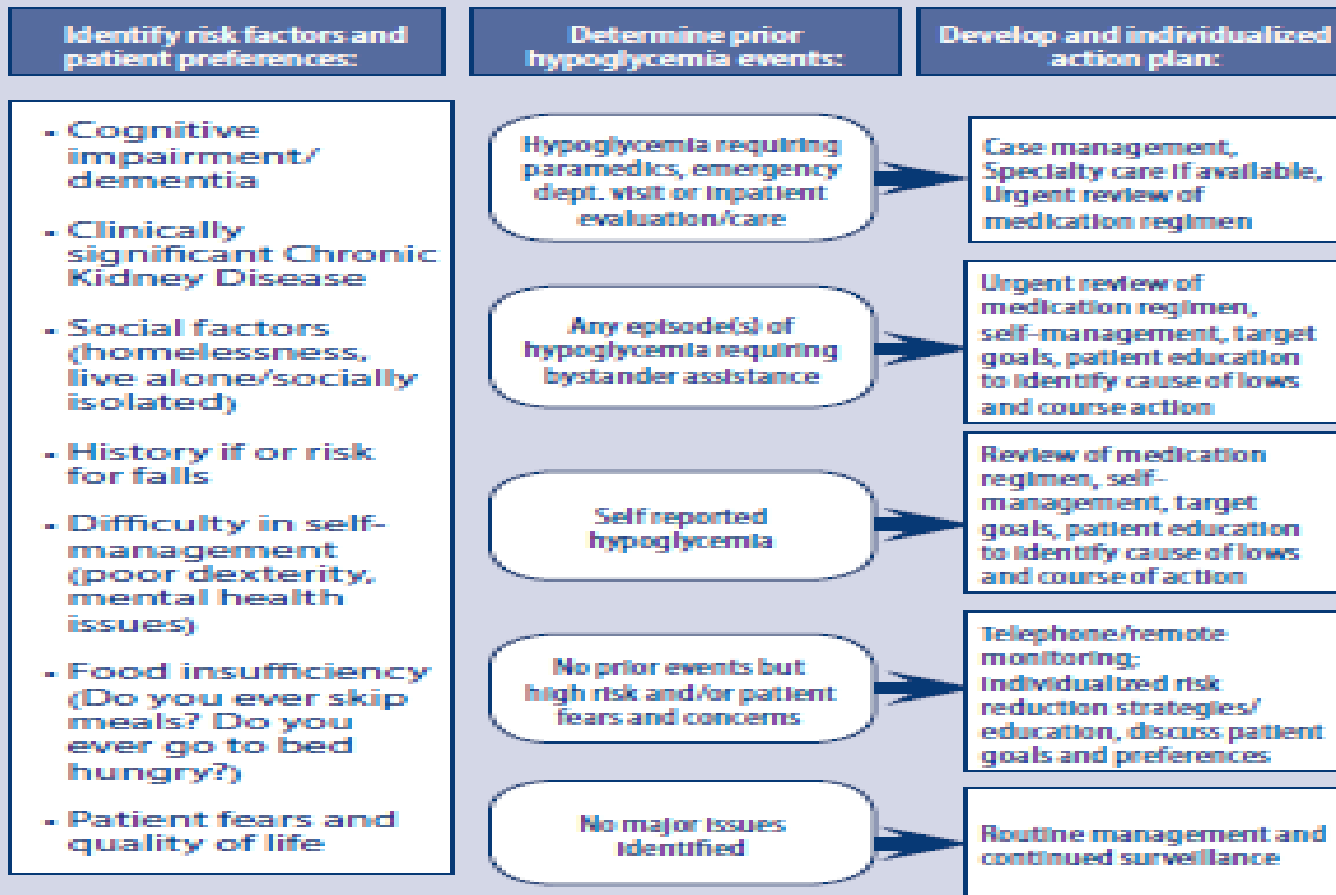
Goal: 8.0-9.0%

- “...**8.0-9.0%** for patients with type 2 diabetes with life expectancy < 5 years, significant comorbid conditions, advanced complications of diabetes or difficulties in self-management” – Weak for
 - 8.0%-9.0% is appropriate for life expectancy <5 years
 - Surrogate markers for life expectancy can include:
 - Functional status
 - Multiple recent hospitalizations
 - Organ failure
 - Cancer diagnosis/treatment plans
 - Advanced medical directives

Food insecurity Screening Algorithm. In the 3 months, were there times when the food for you just did not last and there was no money to buy more?



RISK STRATIFICATION TOOL FOR HYPOGLYCEMIA AND ACTION STEPS

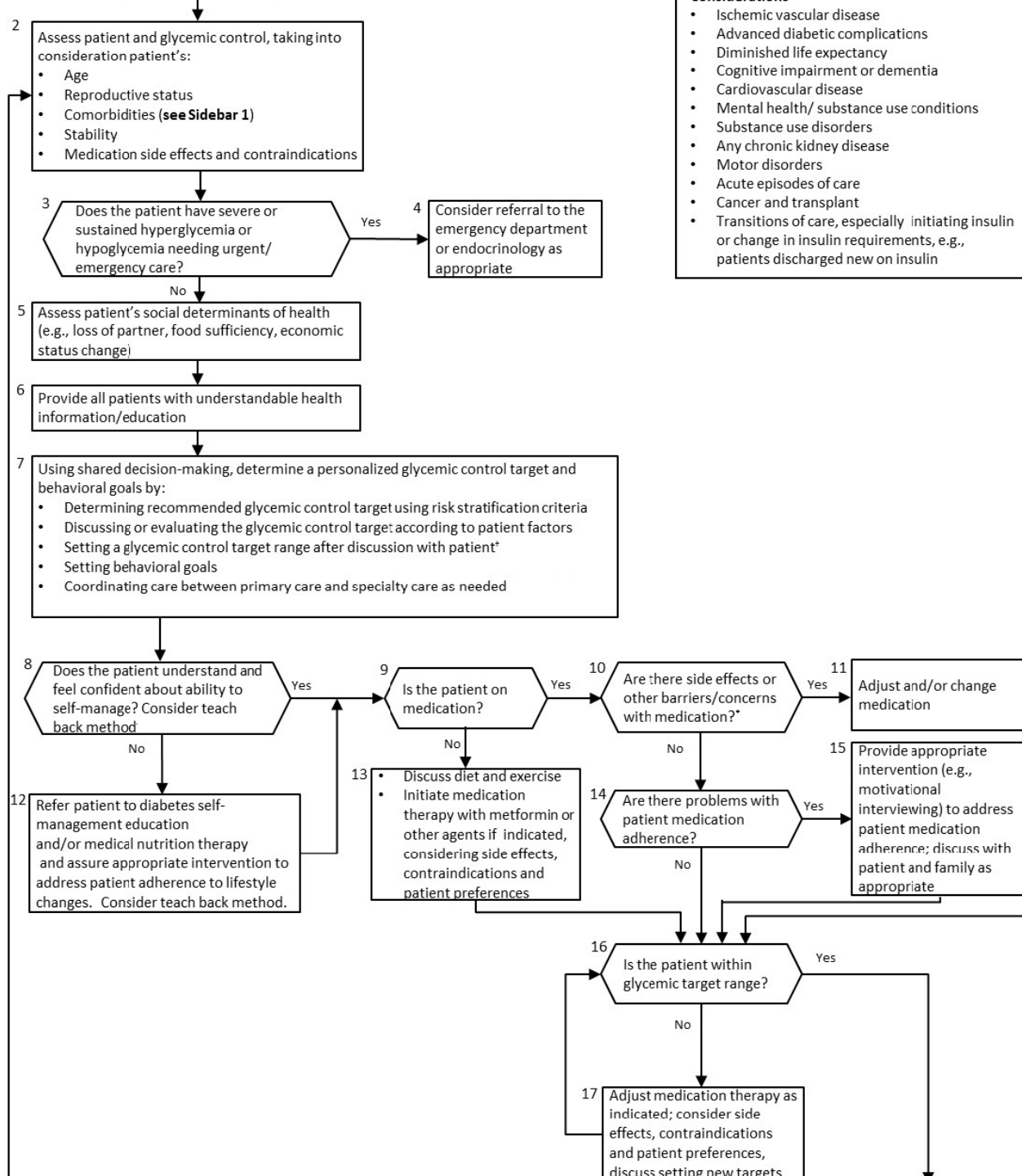


This tool will assist clinicians to assess and address patients' risk for hypoglycemic events of any severity while using oral hypoglycemic prone medications or insulin. Use this tool to increase your awareness of hypoglycemia as a common and important, yet potentially preventable, complication of therapy. It should not be used as a clinical guideline.

Developed in collaboration with the Federal Interagency Work Group-Diabetes Agents /Department of Health and Human Services (5/2017)

Synopsis of the 2017 VA/DoD Clinical Practice Guideline: Management of Type 2 Diabetes Mellitus

- Patients cannot effectively participate in care and share decisions unless they understand diabetes and how they can be involved in planning and carrying out the jointly developed diabetes care plan.
- Conveying complex information in an understandable manner to individual patients and families through a formal process of Shared Decision Making is thus foundational to setting and revising goals that are meaningful, and hopefully achievable, in every day clinical practice



- Ischemic vascular disease
- Advanced diabetic complications
- Diminished life expectancy
- Cognitive impairment or dementia
- Cardiovascular disease
- Mental health/ substance use conditions
- Substance use disorders
- Any chronic kidney disease
- Motor disorders
- Acute episodes of care
- Cancer and transplant
- Transitions of care, especially initiating insulin or change in insulin requirements, e.g., patients discharged new on insulin

Shared Decision Making

VHA Choosing Wisely – Hypoglycemia Safety Initiative

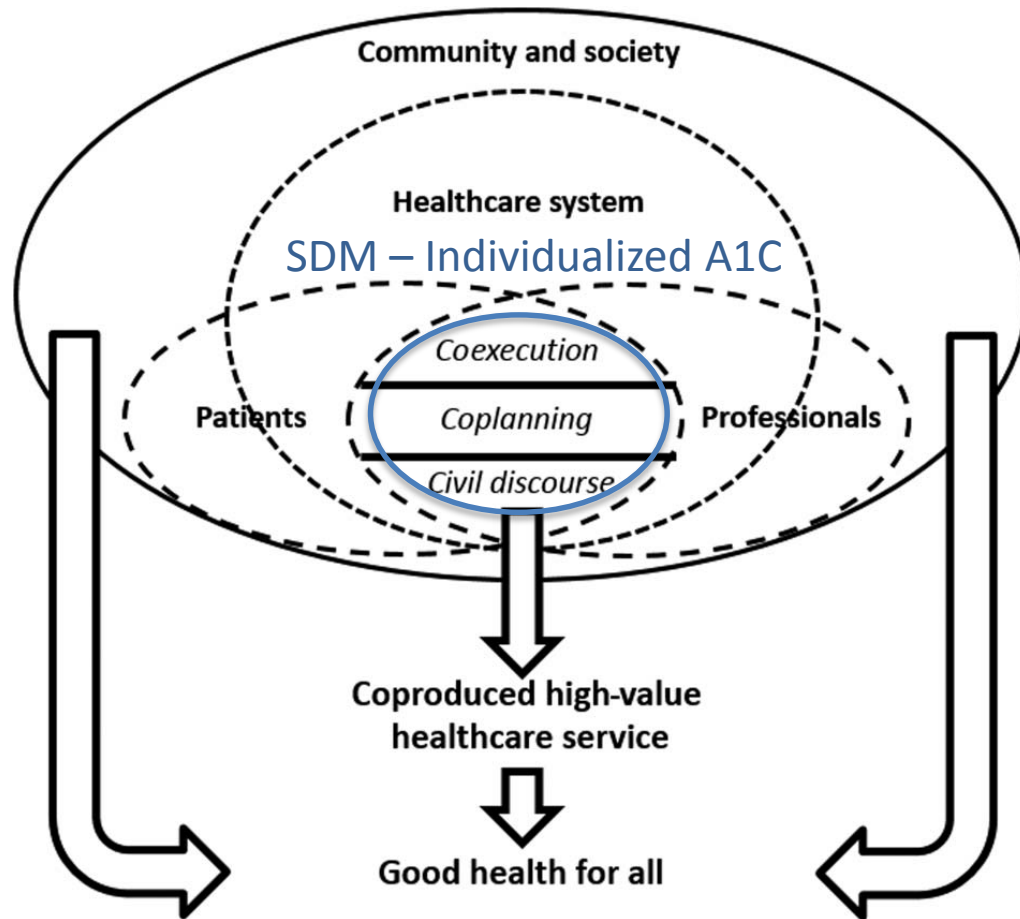
Brian V. Burke, MD, FACP
Chief Diabetes Service, Dayton VAMC
Wright State University

Supported by the VHA Choosing Wisely Task Force
Chartered May 2014

Basis for Shared Decision Making

- Informed Consent
 - Without choice, true informed consent is impossible. White MK et al., JCOM 2003
- Preference-Sensitive Care
 - Represents around 30-35% of all medical care and occurs for conditions where two or more treatment alternatives exist with different risks and benefits or when the benefits/harm ratios are scientifically uncertain. O'Connor AM et al., Modifying Unwanted Variations in Health Care: Shared Decision Making Using Patient Decision Aids, Health Affairs 2004
- (SDM) principles extend the concept of informed consent beyond that of simple information transfer towards honoring informed preferences. King JS and Moulton BW. American Journal of Law & Medicine 32 2006: 429-501
- Patient Centered Care Institute of Medicine (IOM). Crossing the Quality Chasm: A New Health System for the 21st Century. Washington, D.C: National Academy Press; 2001.

Chronic Disease Outcomes are Coproduced Especially in Diabetes



Challenges in Reducing Over-treatment

Measures

- Inconsistent with Guidelines
- NCQA/HEDIS
- Bridges to Excellence

SDM Gaps

- Provider Cognitive Inertia
- Patient Expectation
- Decision Aids
- Trainers

EMR: Failure to Identify at Risk Patients

- Risk
- Severity

Lack Coordinated Message

- Consumer magazines
- Professional Organizations
- Lay Leadership
- Health Care Team Coordination

Challenges in Reducing Over-treatment in Diabetes Mellitus

Provider response to a vignette of a 77 y/o male with long-standing T2DM, severe kidney disease, HbA1c 6.5%, receiving glipizide 10mg BID

| | Disagree | Agree |
|---|--------------|--------------|
| I think this patient would benefit if his HbA1c is maintained below 7% | 61.4% | 38.6% |
| I worry that this patient would be harmed if his HbA1c is maintained below 7% | 44.9% | 55.1% |
| I would worry that reducing his diabetes medication would lead to an HbA1c that falls outside of current performance measures | 57.9% | 42.1% |
| It would be helpful to have a clinical decision-support tool that would help me determine whether this patient would benefit from reducing his diabetes medications | 30.8% | 69.2% |
| It would be helpful to have patient education materials to discuss reducing diabetes medication | 14.6% | 85.4% |

Challenges to Implementing Shared Decision Making for Hypoglycemic Safety

- **Time, Expense and Resources**
 - Lack of adequate decision aids describing hypoglycemic risk
 - Providers: “I’m already doing this”
- **Communication Challenges**
 - Low levels of patient health literacy and numeracy
 - Cultural backgrounds may differ
 - Gaps in patient-physician trust
- **Patient Needs and Expectations**
 - Providers: “Patients do not want to know all of the risks”
 - Half the time patients prefer physicians “best advice”

Adapted from King JS and Moulton BW. American Journal of Law & Medicine 32 2006 and Elwyn G et al., JGIM 2012

AHRQ SHARE MODEL

STEP

1



Seek your patient's participation.

STEP

2



Help your patient explore & compare treatment options.

STEP

3



Assess your patient's values and preferences.

STEP

4



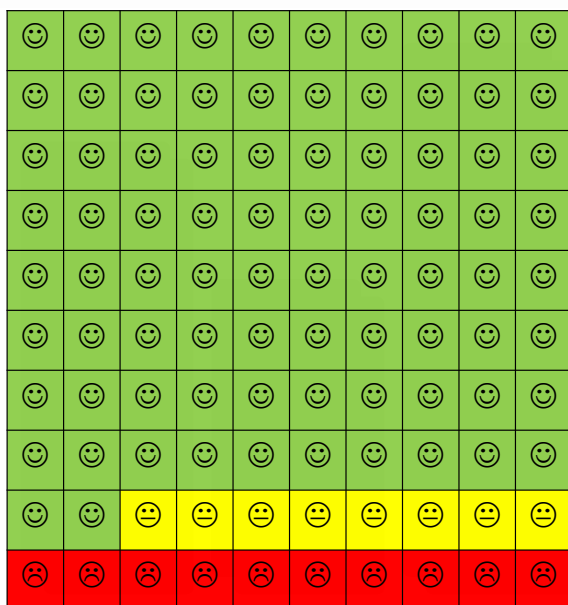
Reach a decision with your patient.

STEP

5



Evaluate your patient's decision.



For new onset diabetes, if A1c levels are targeted to be around **7%** for the first 10 years

82 alive with diabetes without microvascular disease

8 alive with diabetes and microvascular disease

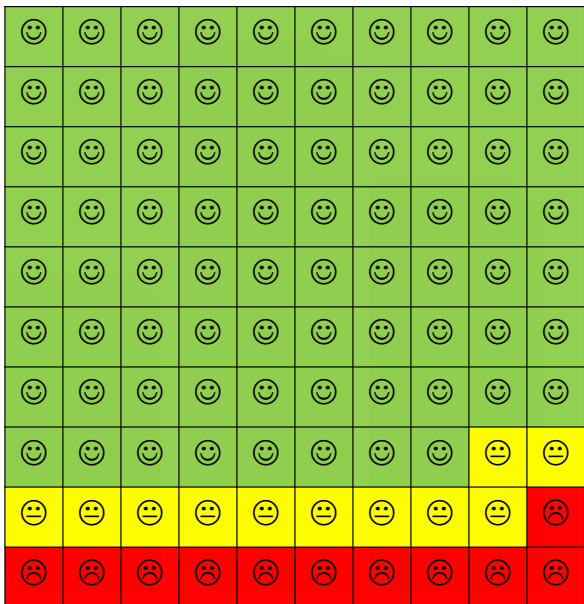
10 dead from diabetes

For new onset diabetes, if A1c levels are targeted to be around **8%** for the first 10 years

78 alive with diabetes without microvascular disease

11 alive with diabetes and micro-vascular disease

11 dead from diabetes



The United Kingdom Prospective Study (UKPDS), conducted from the mid-1980s to late 1990s with patients whose average A1c was 9% at time of diagnosis, **provides the primary evidence base for tight control of type 2 diabetes from onset of disease for individuals with a life expectancy of around 10 years** - UKPDS 33 (sulfonylurea/insulin therapy compared to conventional therapy – Lancet 1998); Use of metformin may confer additional benefit; UKPDS 34 (metformin vs. conventional therapy Lancet 1988).

| | |
|--|--|
| | Person alive with diabetes and no microvascular complications |
| | Person alive with diabetes and with microvascular complications |
| | Person dead from diabetes |
| | Microvascular complications include retinopathy, nephropathy, and neuropathy |

VA Virtual Medical Center Pilot

- Health Professional Education: Shared Decision Making Decision-Simulation based on 3 clinical scenarios addressing Hypoglycemic Safety
- Synchronous Diabetes Self-Management Education employing flipped classroom pedagogy (planned)
- Synchronous and Asynchronous Health Professional training for Shared Medical (Group) Medical Appointment implementation (planned)





**Healthy
Living**

Ask about Low Blood Sugars

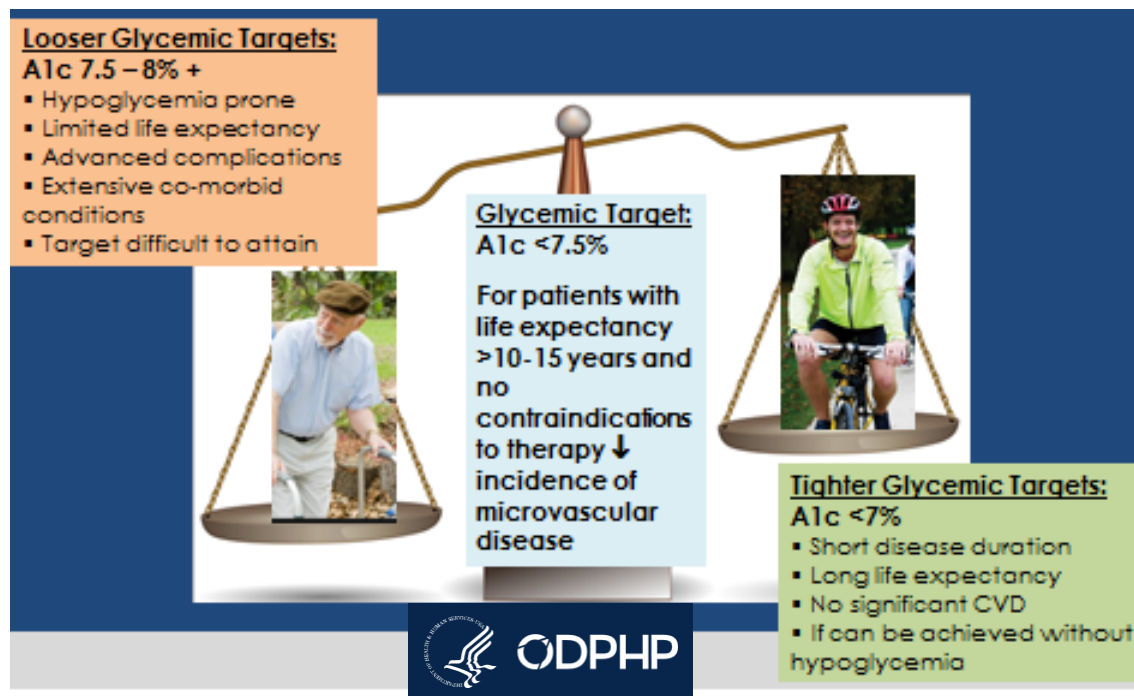
Tom's Story: Be Aware Ask About Low Blood Sugar

<http://videos.va-ees.com/default.aspx?bctid=5476595850001>



Shared Decision Making

Shared Decision Making with the patient when choosing **INDIVIDUALIZED** goals of therapy is key



Mission: Sharing Decisions on Diabetes Care

To create an individualized diabetes care plan that will:

- Be safe and effective
- Accommodate the patient's goals, priorities and lifestyle
- Make it easier for the patient to successfully manage diabetes on a day-to-day basis

Sharing Decisions on Diabetes Care Plans

- Help patients understand diabetes and confidently discuss their needs, lifestyle, goals and the diabetes care plan with their providers and teams, including:
 - Joint discussion with their providers and teams on a safe and effective glycemic target
 - Identifying treatment options to help patients effectively manage diabetes on a day-to-day basis and achieve the glycemic target they agreed on
 - Helping patients actively problem-solve when life and diabetes don't go as planned
 - Course correction as needed
- The ultimate goal: Patients, providers and health care team will discuss and share decisions to create personalized diabetes care plans that permit patients to successfully manage their diabetes over the long-haul and achieve optimal health.
- **How can we do this**

Use Teach-Back to determine in 1-2 minutes if your explanation was clear. Here are some examples:

- “We talked about two ways that you might be able to treat your diabetes: either starting medicine right away to lower your blood sugar or increasing your physical activity and following a Mediterranean diet to try to lose a little weight. I want to make sure I explained each option clearly. Would you please tell me how you would explain the two choices to a member of your family?”
- “I want to make sure I was clear about the risks and benefits of taking insulin to control your diabetes. Could you tell me about insulin’s possible side effects and how it might impact your life on a day-to-day basis?”
- “I want to check how well I explained the risks and benefits for a patient like you, of a higher Hemoglobin A1c target of 8 rather than 7. Please describe, in your own words, what are the pro’s and con’s of raising your target Hemoglobin A1c to 8.”

If the patient is unable to describe, say “I must not have done a good job explaining. Let me try again.” And use a different approach. Remember, it’s THE CLINICIAN’S responsibility to be clear, NOT the patient’s responsibility to understand.

Patient & Provider Educational Resources

VA/DoD Guidelines

- <https://www.healthquality.va.gov/>

National Center for Health Promotion and Disease Prevention

- <https://www.prevention.va.gov/>

Patient Facing Videos – “Patients as Partners”

- <https://www.youtube.com/watch?v=yAeJYFR5nKo> Tom’s Story
- https://www.youtube.com/watch?v=lqX_2ffEtZw Mary’s Story
- <https://www.youtube.com/watch?v=Ol-hzi2HSYg> Joe’s Story

VA Nutrition & Food Service

- <https://www.nutrition.va.gov/>

In order for SDM to be effective Patients must understand the pro's and con's of possible treatment options

How do we do this?

- Provide health information that patients can easily understand and act on
- The Veterans Health Library's (VHL) , www.veteranshealthlibrary.org information on diabetes is Veteran-focused in content and design
 - All VHL health sheets, interactive guides and videos have been vetted by VHA diabetes subject matter experts
 - 3 videos which demonstrate patients discussing low blood sugars with their providers and teams
 - Interactive SDM tool for patients on whether to add insulin to the treatment plan permits patients to explore their values and the pro's and con's of this decision, and be ready to discuss with their provider.
- Ensure that our explanations are clear and if not, try to explain in a different way

References

1. Management of Diabetes Mellitus. VA/DoD Clinical Practice Guideline. Available at: <http://www.healthquality.va.gov/guidelines/CD/diabetes>
2. U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion. (2014). National Action Plan for Adverse Drug Event Prevention. Washington, DC: Author.
3. Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models; Proposed Rule, 81 Fed. Reg. 89 (May 9, 2016). *Federal Register: The Daily Journal of the United States*. Web. 14 October 2016.
4. Feil DG et al. Risk of of hypoglycemia in older veterans with dementia and cognitive impairment: implications for practice and policy. *J Am Geriatr Soc*. 2011 Dec;59(12):2263-72.
5. Caverly TJ et al. Appropriate Prescribing for Patients With Diabetes at High Risk for Hypoglycemia: National Survey of Veterans Affairs Health Care Professionals. [JAMA Intern Med](#). 2015 Dec;175(12):1994-6.
6. Batalden M, Batalden P, Margolis P, et al. *BMJ Qual Saf* 2016;25: 509–517